GE Healthcare

Performa

Operation Instructions

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37094-IMG rev 3

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GE Healthcare Finland Oy, a General Electric company, going to market as GE Healthcare.

This manual applies to Performa units with software version 7.71a and up.

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1 Introduction

1.1 General

Performa is a high quality x-ray mammography unit intended for both screening and diagnostic examinations. The main features are the rotating dual-angle anode tube, **T**uned **H**igh **F**requency (**THF**) generator and easy positioning of the patient.

The vertical adjustment is motorized, and the C-Arm rotation angle ranges from +135° to -180° degrees. The motorized compression of the breast is controlled by pedals, and the manual compression by manual control. If wanted, the compression can be released automatically after exposure. In power failure the compression is released automatically.

The **THF** generator is integrated with the unit. The control panel can be mounted on either side of the unit or on the wall of the examination room. The exposure button can be situated beside the control panel or outside the examination room.

The functions of the unit are controlled by a microprocessor, and the operator is informed of error situations. For example, exposures without cassette or too large diaphragm are prevented.

The **Performa** is intended only for mammographic examinations, no other uses are permitted.

NOTE!

Move the foot pedals away from the working area to prevent any unwanted activations of compression.

WARNING!

Never use the equipment if it is suspected that any electrical, or radiation-emitting component is defective or inoperative.

WARNING!

Only trained, licensed persons are allowed to operate the Performa unit.

WARNING!

USE LIMITATION : External components: The use of accessories, transducers, and cables other than those specified may result in degraded ELECTROMAGNETIC COMPATIBILITY of the EQUIPMENT and/or SYSTEM.

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WARNING!

If you suspect any electro-magnetical interference affecting or caused by the unit, call service. Portable and mobile RF communications equipment can interfere with operation of the medical electrical equipment.

Both cassette sizes, 18 x 24 cm and 24 x 30 cm can be used.

GE Healthcare accepts no responsibility for safety, reliability or the performance unless:

- Assembly, calibration and repairs are performed by an GE authorized representative according to corresponding Performa manuals.
- Any modification, addition or deletion to this system is authorized specifically by GE, in writing.
- Electrical installation complies with the IEC regulations.
- The system is used in accordance with Operating Instructions.

This device emits X-ray radiation for medical purposes. X-ray tube has molybdenum anode. X-rays are molybdenum or rhodium filtered. Minimum HVL 0,3 mmAl without compression paddle. Performa is CE-marked in accordance with MDD (93/42/EEC). Performa fulfills the EMC requirements of IEC 60601-1-2 2.ed.

1.2 RADIATION PROTECTION

As radiation is harmful to human body, the radiation protection regulations of individual countries must be complied with. The user must have a permission to use x-ray device for mammography. Radiation protection means should be used. Prior to examination, it is recommended to make sure that the doctor knows if the patient is pregnant. If someone has to be close to the patient, protective clothing must be used.

The optional RADIATION SHIELD must be used, or the unit must be operated from a shielded control room (significant zone of occupancy is 2 meters). During the exposure, visual and audible contact should be maintained with the patient. The free-standing radiation shield can be positioned as required in the X-ray room. A mammography accessory storage unit is available as an option and may be placed behind the free-standing radiation shield.

CAUTION!

The maximum radiation that the system is capable of producing corresponds to 5% of the typical CT-radiographic exposure. However, the user should wear a dose recording device and follow local regulations for radiation protection.

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1.3 CONVENTIONS IN THIS MANUAL

The manual has following conventions:

NOTE!

Contains useful information for the reader about the unit and its use.

CAUTION!

Contains important instructions. If these instructions are not observed, malfunction of the unit or damage to the unit or other property may occur.

WARNING!

Contains warnings and instructions about the safety of the unit. If these warnings are not respected, serious risks and injury may be caused to the patient and operator.

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2 Operation controls

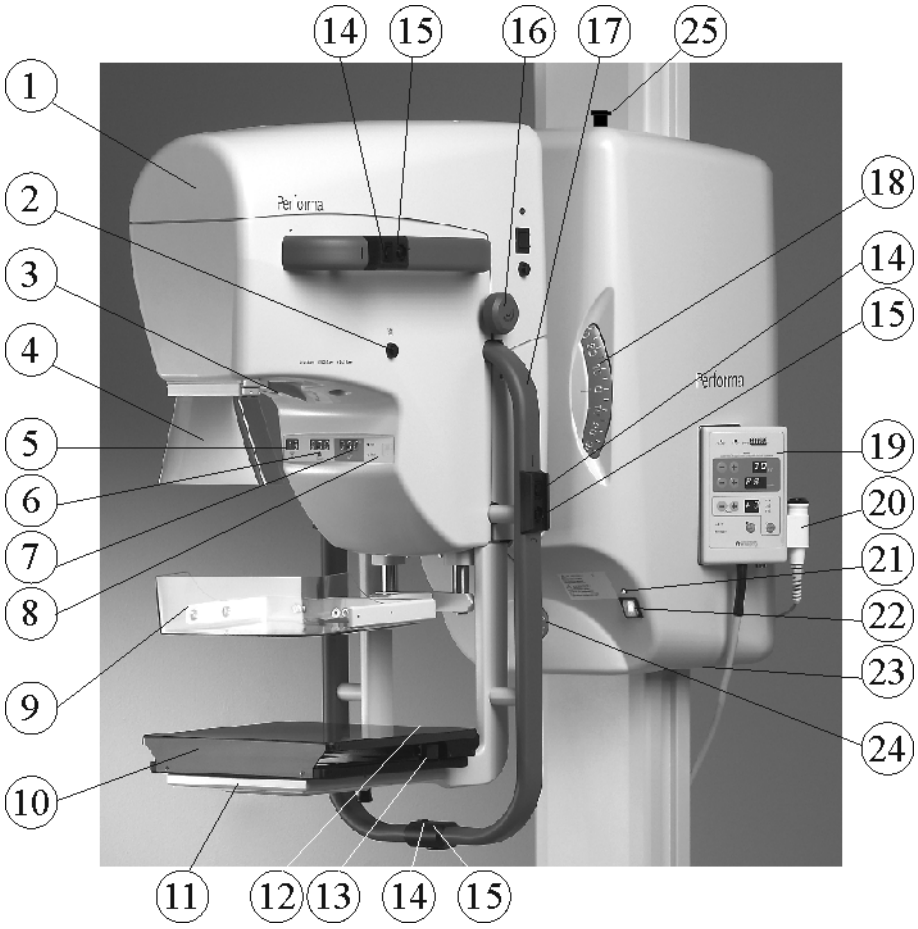

Fig 2.1. The stand

1	X-ray tube	13	Spring for cassette locking
2	X-ray field illumination light	14	Toggle switch for vertical drive control
3	Diaphragm selection lever	15	Button for C-Arm brake release
4	Face shield	16	Manual controls for compression
5	Compression thickness display	17	Hand grips
6	Compression force display	18	Rotation angle disc
7	Digital display of image angle	19	Control panel
8	Beam filter selection and indication	20	Exposure button
9	Compression paddle	21	Indication of mains plug (Illuminated if automatic fuse on)
10	Cassette holder	22	Mains switch
11	Automatic exposure control detector (VectorPoint)	23	Automatic fuse
12	Detector position display (VectorPoint)	24	Compression force limit adjustment
25	Emergency stop button (on both sides of the unit)		

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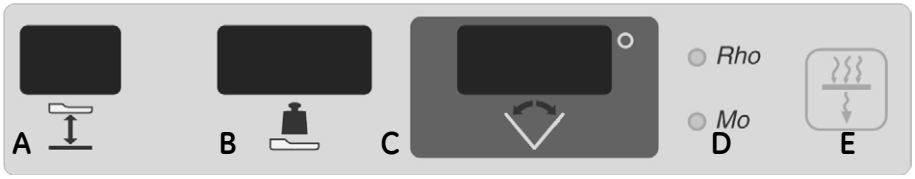

Fig 2.2. C-Arm display (A: Breast Thickness (cm), B: Compression force (N), C: C-Arm angle (°), D: Filter, E: Filter selection)

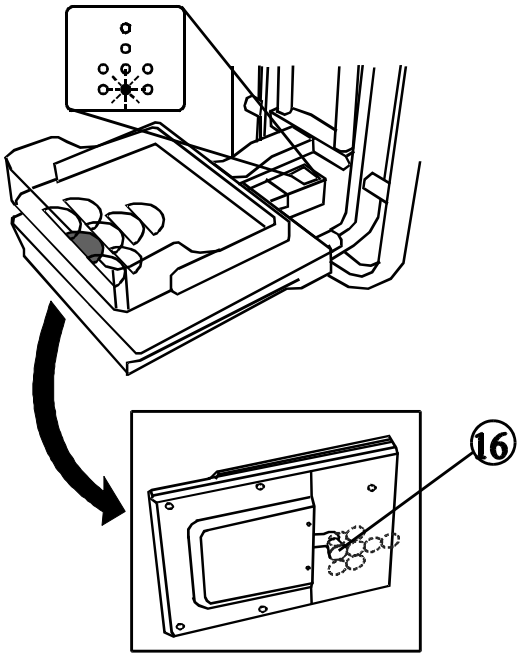

Fig 2.3. Automatic exposure control detector (VectorPoint)

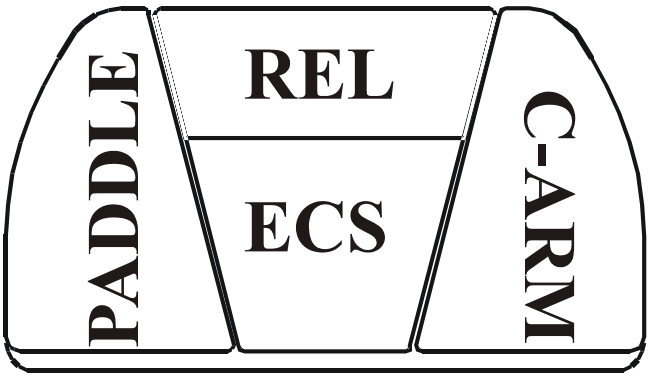

Fig 2.4. The ECS Pedal for compression and X-ray field illumination light switch

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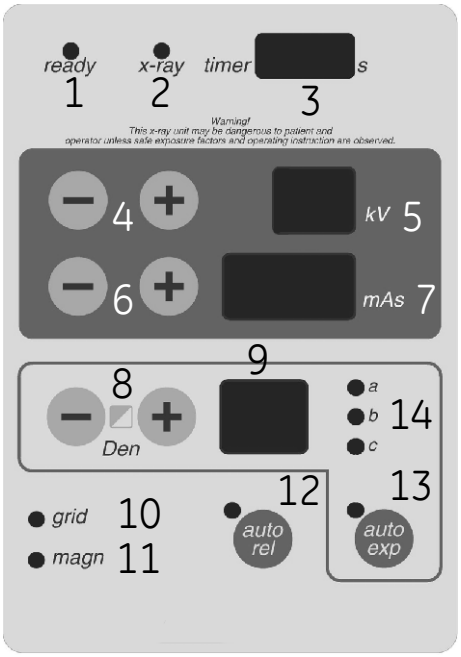

Fig 2.5. Control panel

1 Ready indicator
2 Radiation indicator
3 Display of exposure time and error codes
4 kV selection
5 kV display
6 mAs selection
7 mAs display
8 Density selection
9 Density display
10 Grid and Bucky indicator, large focus
11 Magnification indicator, small focus
12 Button and indicator for automatic compression release
13 Button for selection of Auto-kV, Semi AEC or manual mode or acknowledging error messages
14 AEC program indicators

NOTE!

When “grid” light is displayed, the large focal spot is selected. When “magn” light is displayed, the small focal spot is selected.

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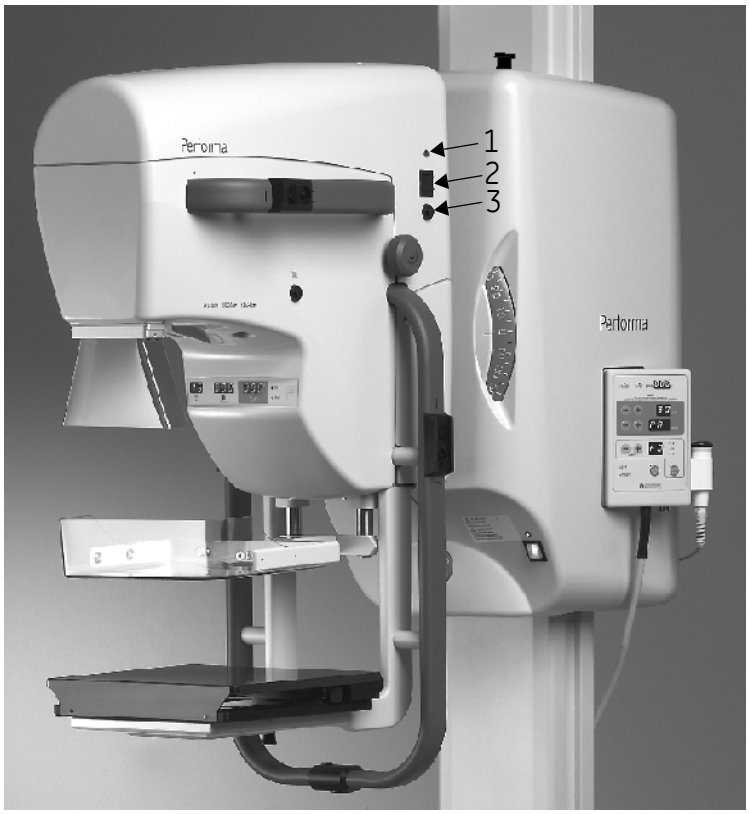
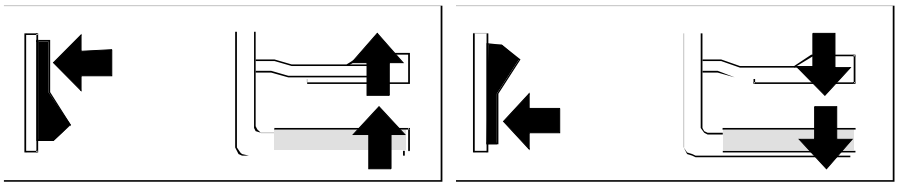


Fig 2.6. The ECS cover buttons

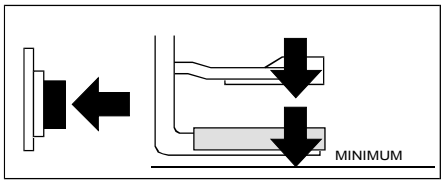
NOTE!

In the Great Britain (GB) model toggle switch (2) and return button (3) are functional only when compression is fully released.

1 Balance indicator (if illuminated the C-Arm is not in balance and the C-Arm brake can not be released, press return button (3))



2 Toggle switch (2) for vertical movements of C-Arm and paddle



3 Return button (Returns the C-Arm in the balance)

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3 Operation procedure

3.1 PREPARATIONS

3.1.1 Switching on the unit

⚠ WARNING !
When the light is on parts of the system are energized although power switch is off.

⚠ ATTENTION !
Lorsque ce voyant est allumé, cela indique que certaines parties du système sont sous tension bien que l ' alimentation électrique soit coupée.

324-58

Notice the warning label next to the power switch. Use the circuit breaker located in the back of the carriage In order to switch the power off completely.

Switch the power ON using the mains switch. The timer display now shows r.ES, kV display Pr, mAs display shows the software version and density display shows the country code. Resetting must be acknowledged by pushing the auto exp button, which starts the internal testing routine.

The power can be kept on between the examinations, but it is recommended to keep the unit turned OFF from mains switch when not in use. Switching ON and OFF restores the default settings on the control panel. It is recommended to allow a warm-up period of approximately 3 minutes after the unit is switched on.

3.1.2 Replacement of the accessories

NOTE!
All accessories that the Performa manufacturer supplies for Performa are suitable within the patient environment, unless otherwise indicated.

The following accessories are available for the unit (for more information, refer to ACCESSORIES LIST 31581):

- 18 x 24 Semicircular diaphragm
- 18 x 24 cassette holders
- 18 x 24 Bucky devices

- 24 x 30 semicircular diaphragm
- 24 x 30 cassette holders
- 24 x 30 Bucky devices

- 10 x 24 cm compression paddle
- 21 x 24 cm compression paddle
- 21 x 24 cm XXL compression paddle
- 24 x 30 cm compression paddle
- 24 x 30 cm XL compression paddle for extra large breasts
- 24 x 30 cm XXL compression paddle for extra large breasts
- 21 x 20 cm compression paddle
- spot magnification tunnel (1.6 X)
- magnification kit (1.6 X, 1.8 X, 2.0 X and MammoSpot 1,6 X)
- magnification diaphragm
- magnification tunnel
- magnification compression paddle
- spot magnification compression paddle
- spot diaphragm
- spot kit for contact use
- biopsy and needle localization compression paddles

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NOTE!

If the selected diaphragm is larger than the film, the exposure is prevented and a C.CO error code is displayed

The **18 x 24** and **24 x 30 cm rectangular diaphragms** are integral parts of the collimator.

The **18 x 24 cm rectangular diaphragm** is selected by pushing the diaphragm selecting knob towards the unit.

To select the **24 x 30 cm diaphragm** pull the knob.

To install a **special diaphragm**, slide the plate into the groove in the direction of the patient, and snap the plate into place. Refer to figure below.

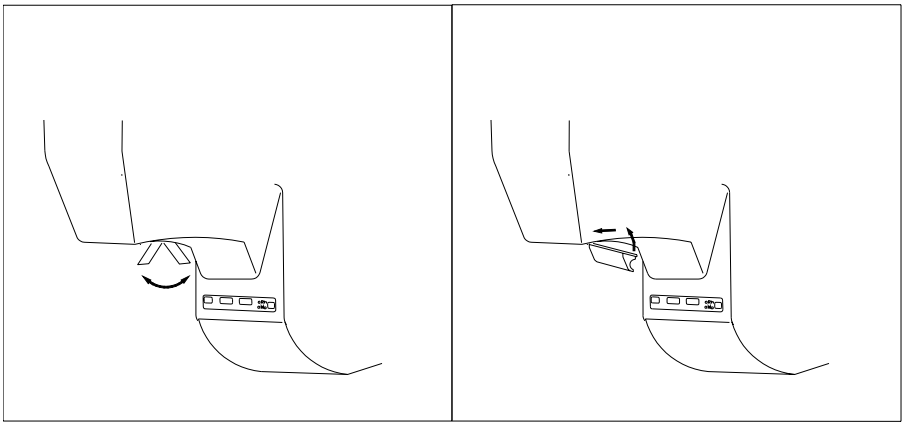
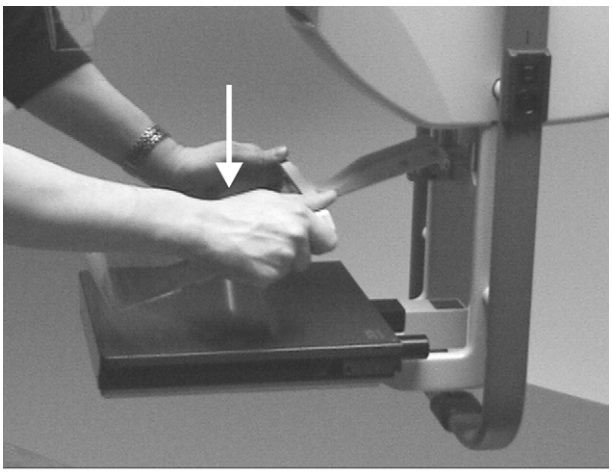


Fig 3.1. Selecting diaphragm and replacement of special diaphragm

Replacement of compression paddles:

Press down the compression paddle and pull it out.



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Insert the desired paddle into the groove and push the paddle upwards until it locks.

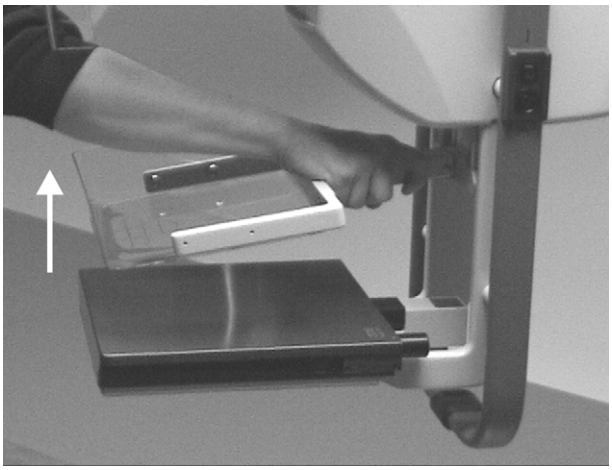
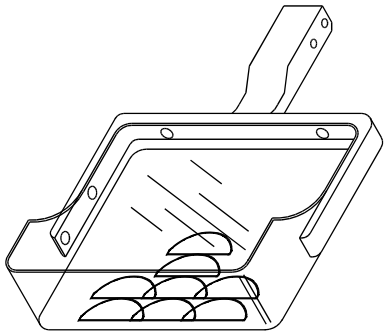


Fig 3.2. Replacement of compression paddle

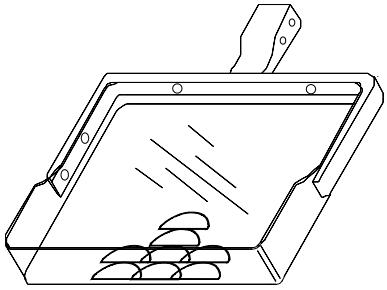
21x24 cm compression paddle



The 21x24 cm compression paddle is the standard paddle used with the 18x24cm film format with the bucky or cassette tunnel.

It must not be used with the larger 24x30cm film and the corresponding cassette holders because it does not apply compression to the whole breast being imaged, especially to the upper quadrant of the breast in oblique and lateral views.

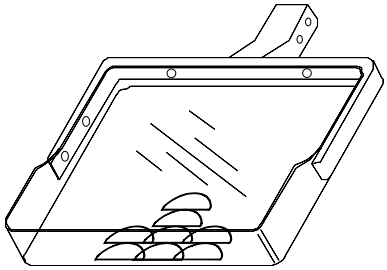
24x30 cm compression paddle



The 24x30 cm compression paddle is used with the large bucky or cassette tunnel.

It applies compression to the whole breast being imaged.

XL or XXL compression paddle



These paddles allow very thick breasts to be positioned because those give additional space in between the paddle and the cassette holder: XL (+3cm) and XXL (+5cm).

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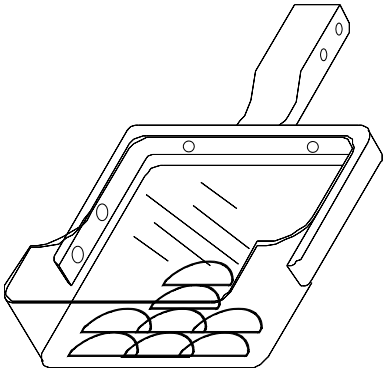
NOTE!

When using AA-mode with XL or XXL compression paddles, select higher kv than Performa automatically proposes.

20x21 cm compression paddle

The 20x21 cm compression paddle is narrower than the standard 21x24 cm paddle.



Therefore, during positioning it allows a better access to a small breast.

In oblique or lateral views it allows a better compression to breast if the size of the axillary muscle does not allow the use of the standard paddle.

It is important to remember, however, that especially in the oblique view the axillary muscle is of interest because 45% of lesions are in the upper, outer quadrant of the breast.

Replacement of cassette holders

Align the guides of the desired cassette holder with the grooves on the C-Arm. Push the cassette holder to its position. The Bucky devices and magnification tunnel are replaced in the same way.

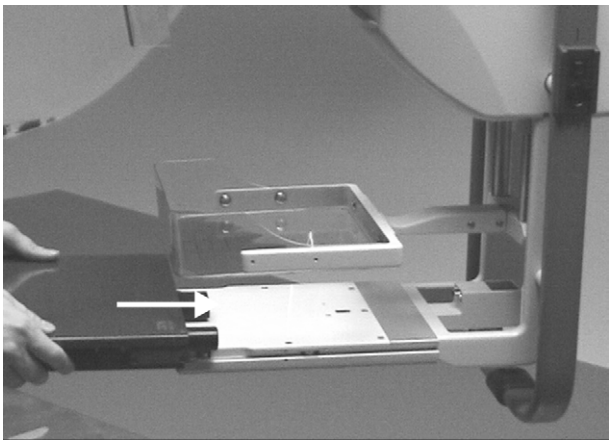


Fig 3.3. Replacement of cassette holder

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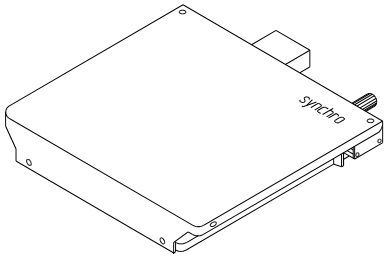
Exposures with the Bucky device

Install the Bucky device as shown in Fig. 3.3, Replacement of cassette holder. The grid indicator will light up.

Patient positioning and exposure techniques are similar to those described in sections 3.6, Patient positioning and 3.7, Exposure procedure When using the Bucky device kV-values must be 2-3 kV higher compared to exposures with cassette tunnel.

A bucky is the most often used cassette holder in mammography.



It has a moving grid inside which is to reduce the amount of scatter radiation reaching the film.

Primary radiation goes directly through the breast and the grid and produces the image of the breast on the film.

Scatter radiation has an arbitrary angle and thus produces no image on the film but only reduces the contrast in the final image.

There is a separate bucky for both film formats 18x24 and 24x30 and for both cassette types, normal cassette and daylight cassette.

Exposures with the Cassette tunnel

The purpose is to maximize the image quality by having the object to film distance as short as possible which reduces blurring and by being able to use a low kV-setting because of low attenuation in the cassette holder itself.

The cassette tunnel, however, has no means of reducing the scatter radiation to the film and this reduces the contrast considerably. Therefore in many countries the cassette tunnel is not a recommended or not even an allowed cassette holder.

There is a cassette tunnel for both film formats, 18x24 and 24x30 cm and for both cassette types, normal cassette and daylight cassette.

NOTE!

See more information of accessories in section **Special exposures**.

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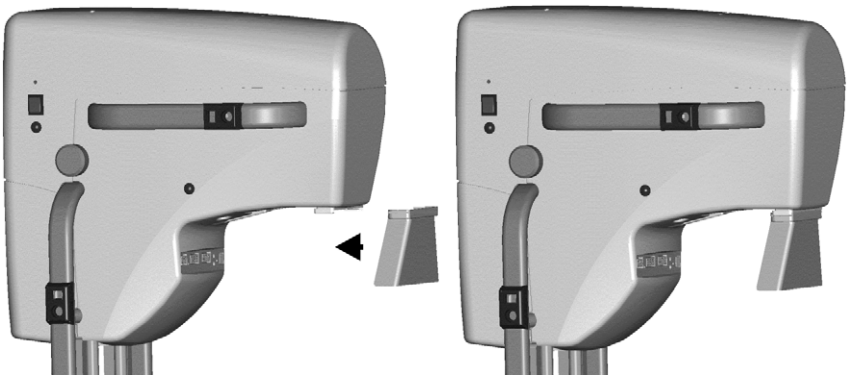
Face shield

Face shield is used to keep patient's face out of x-ray beam during exposure.



Face shield is installed by sliding it in along the grooves until the magnetic lock is set. Remove the face shield by pulling it out along the grooves until the magnetic lock is released.

3.2 SELECTION OF THE TECHNIQUE FACTORS

There are three modes of operation:

- Full automatic AEC (Auto-kV)
- Semi automatic AEC
- Manual mode

Select the mode with the button for automatic exposure button. The light at the corner of the button indicates that the AEC operation is selected, mAs display indicates **AA** if Auto-kV is selected and **A** if semi automatic AEC is selected, refer to Fig.3.4, Control panel in Auto kV or semi AEC mode.

A **Operation in Auto-kV and in Semi AEC mode**

In the Auto kV mode the exposure time and the kV are automatically selected to produce an optimum image quality.

In Semi AEC mode only the exposure time is automatically selected to produce an optimum image quality.

There are three preprogrammable stations for each automatic mode:

Station **a**: Default selection
Station **b**: Press once the **AUTO EXP** button
Station **c**: Press again the **AUTO EXP** button

1 As the factory default the system starts in **AA mode**, you need to select **semi AEC mode**. Press **AUTO EXP** so many times that the mAs indicator displays A. In this mode the exposure time is automatically selected. The kV is manually selected.

For **manual mode** selection, press **AUTO EXP** so many times that the mAs indicator displays a mAs value and the **AUTO EXP** light indicator turns off.

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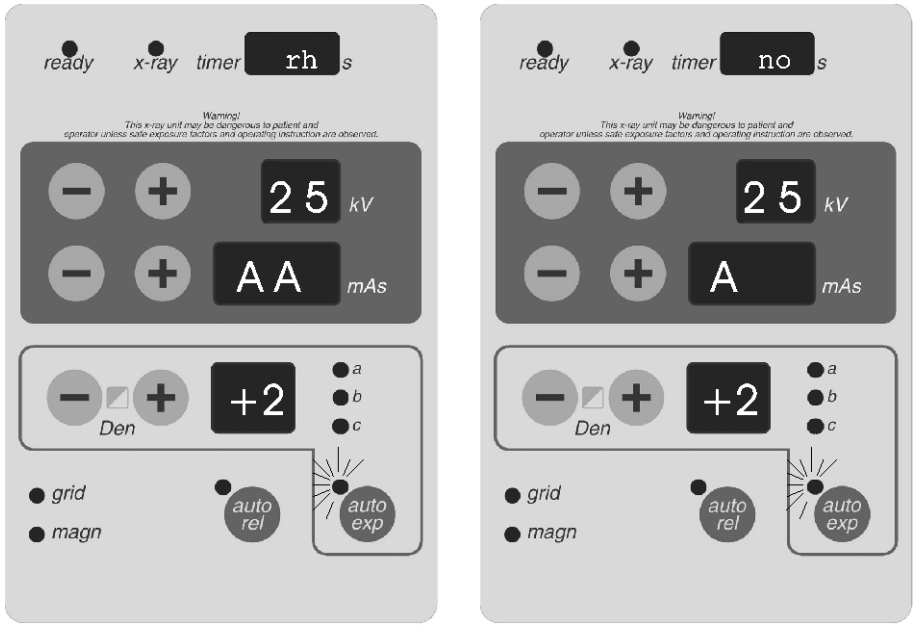
2 Select the kV with the kV selection buttons. If Auto kV is selected, the kV is automatically selected.

In automatic modes the tube voltage range is 23 kV - 35 kV for large focus, 25 kV - 35 kV for small focus and 20 - 35 kV in manual mode for both focal spots.



Auto kV Semi AEC

Fig 3.4. Control panel in Auto kV or semi AEC mode

NOTE!

In Michigan state mode the kV is limited to 34 kV

Select the **Density** with the density selection buttons. Use **- Density** for lighter images, and **+ Density** for darker images. Each step (nominal and dependent on the phototimer calibration) decreases/increases the exposure time by 10% (default, adjustable through software between 5% - 20%). The range of correction is from -7 to +7.

The **position of the phototimer detector** can be adjusted from the knob under the cassette holder. The **detector location display** indicates where the detector is located corresponding to the breast. The semicircle on the paddle indicates the size and location of the detector.

During exposure, the highest possible mA is automatically selected and used to minimize the exposure time. The **AEC** terminates the exposure when the correct amount of radiation has reached the film. The time range is from 0.04 sec. to 5 sec. when using large focus (bucky, cassette tunnel), and from 0.04 sec. to 10 sec. when using small focus (magnification). The “magn” indicator light on the control panel displays which image receptor device is attached to the system. When the indicator light is lit, the system will automatically select the small focus. When the “magn” light is not lit, the system is using the large focus.

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NOTE!

For country code 12 (Great Britain) the time range is from 0.04 sec. to 6 sec., and maximum mAs is 600 mAs.

NOTE!

In the New York version the maximum exposure time is the time that is needed to achieve 300 mAs.

NOTE!

If a proper optical density could not be reached, even if maximum exposure time would be used, the Exposure monitoring will terminate the exposure in 50 ms. Select a higher kV and make a new exposure. CHANGE THE CASSETTE.

B Operation in the Manual Mode

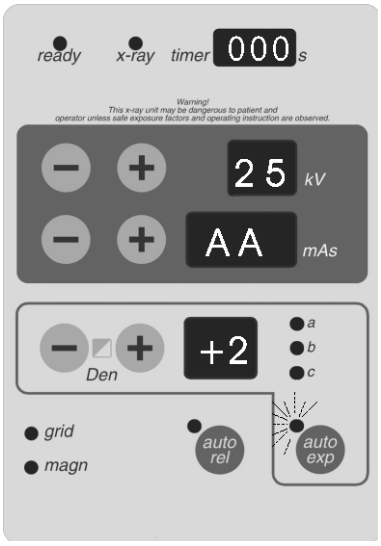

Fig 3.5. Control panel in the manual mode

Select the **mAs** setting with mAs ± keys. Pressing the **mAs+** button increases the value and pressing **mAs-** button decreases the value as shown in Table 3.1.

4	6	12	16	20
25	32	40	50	63
80	100	125	150	175
200	250	300	350*	400*
450*	500*	550**	600**	

Table 3.1 Selection of mAs values

*, ** not allowed in N.Y. ** only allowed in G.B

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The maximum mAs-value is, however, limited by the selected kV and the maximum permitted time. The **maximum mAs/mA** values are shown in table 3.2, Maximum mAs/mA values depending on kV, focus size and country code. Software version 7.71a..

	MGF 110 0.3 focus	MGF 110 N.Y. 0.3 focus	MGF 110 0.1 focus
kV	**mAs/mA**	**mAs/mA**	**mAs/mA**
20	350/75	300/75	250/25
21	400/80	300/80	250/26
22	400/85	300/85	250/28
23	450/90	300/90	300/30
24	450/95	300/95	250/29
25	500/100	300/100	250/28
26	450/95	300/95	250/27
27	450/90	300/90	250/26
28	400/85	300/85	250/25
29	400/85	300/85	200/24
30	400/80	300/80	200/23
31	400/80	300/80	200/22
32	400/80	300/80	200/21
33	350/75	300/75	200/21
34	350/75	300/75	200/20
35	300/69	300/69	200/20

Table 3.2 Maximum mAs/mA values depending on kV, focus size and country code. Software version 7.71a.

3.3 AUTOMATIC COMPRESSION RELEASE

By pressing the automatic release button you can select or de-select the automatic compression release immediately after an exposure. The light at the corner of the button indicates that the automatic release has been selected (default). De-select the feature for example when performing manual biopsy.

NOTE!

The automatic release should be turned off during a needle biopsy procedure.

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3.4 C-ARM ADJUSTMENTS

3.4.1 Vertical adjustment

The cassette holder vertical adjustment range is 40 cm - 144 cm (15" - 56") with the C-Arm in the upright position and 80 cm - 194 cm (31" - 76") with C-Arm at lateral position.

The vertical movement is motorized, and the **control keys** are placed on both sides of the unit. There is a button also at the lower part of handle, used when the C-Arm is tilted (The arrow towards the image receptor indicates downward direction and the arrow pointing away from the image receptor upward direction).

NOTE!

If country code 16 (Australia) is selected, vertical movement starts first after compression fully released.

NOTE!

If country code 12 (G.B.) is selected, vertical movement is inhibited during compression. Release the compression fully to enable vertical movement.(in software version 3.21 and higher).

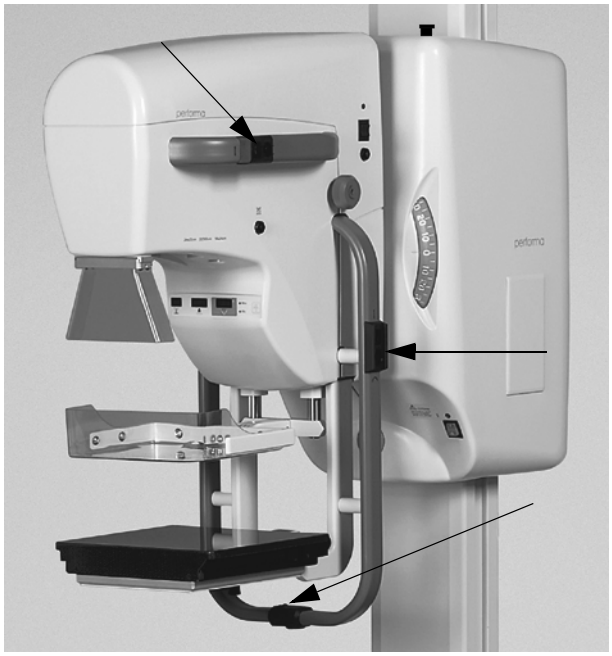

Fig 3.6. Toggle switch for vertical drive control

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3.5 SELECTION OF THE IMAGE ANGLE

The C-Arm rotates from +135° to -180° from the vertical position.

Release the brake by pressing on of the **release buttons** and rotate the C-Arm (figure 3.7, Selection of the image angle).

The image angle can be seen on the digital display (10) located on the C-Arm and also at the scale ring at the C-Arm axle. The angles -135°, -120°, -90°, -60°,-45°, 0°, +45°, +60°, +90° and +120° can be felt as détente points. The C-Arm is locked when the button is released.

NOTE!

If country code 16 (Australia) is selected, compression is released when C-Arm brake is released.

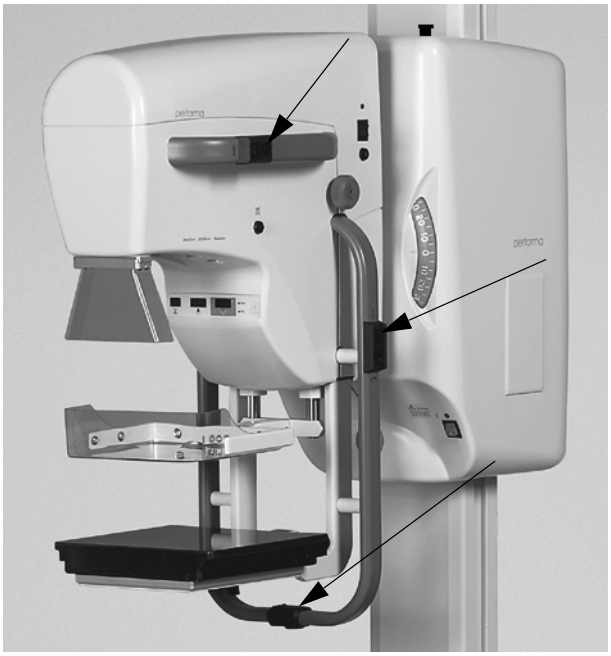

Fig 3.7. Selection of the image angle

3.5.1 Compression

A good image quality requires sufficient compression of the breast. The breast is pressed against the cassette holder by the compression paddle. The compression paddle can be moved with motor **by pedals** or **by manual controls**.

The motorized motion of the compression paddle is controlled **by pedals**. The downward arrow of the pedals indicates compression, and the upward arrow indicates release (Fig. 2.4, The ECS Pedal for compression and X-ray field illumination light switch).

The compression force limit for automatic compression can be adjusted externally with the six-step selector. For safety reasons motorized compression is limited in position 6, for example, to be 200N (44lbs) according to the local demands.

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Remember, care must be taken in order **not to injure the breast**. The compressed breast thickness and the compression force is display in the C-Arm display, refer to page 4.

Manual compression controls are turned clockwise for compression and counterclockwise for release (Fig. 3.8, Compression setting by manual controls). As the manual controls allow considerable compression, **up to 300 N (66 lbs.)**, care must be taken not to injure the breast.

The compression system incorporates also a mechanical force limit which is adjusted to **300 N (66 lbs.)** the factory.

Fig 3.8. Compression setting by manual controls

3.5.2 X-ray field illumination light

The x-ray field illumination light is switched on automatically when pressing the downward **compression pedal** or pressing the **x-ray field illumination light switch**. The figure of the light, next to the downwards arrow indicates this. It is switched off automatically after about 40 seconds, x-ray field illumination light switch is pressed again or when the exposure is initiated.

3.5.2.1 Beam filter selection

For large and dense breasts the **Rhodium filter** should be used to reduce the exposure time and the patient dose. Manual selection of the filter (selected from the **filter button** on the C-Arm) is default, but system can be programmed to change the filter according the breast thickness. The selected filter is indicated with a light next to the filter selection button and on the control panel **timer display** when the unit is in ready position.

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NOTE!

After the exposure the timer display shows the exposure time. After the cassette is removed from the cassette holder, the timer display indicates which filter is in use. mo = Molybdenum filter (0.03 mm), rh = Rhodium filter (0.025 mm).

NOTE!

When using the Rhodium filter do not increase the kV-setting.

3.6 PATIENT POSITIONING

NOTE!

Always advise the patient not to use deodorant prior to a mammogram! Certain deodorants can mimic as microcalcifications on the film.

NOTE!

In case the patient moves in the middle of a procedure or compression thickness is changed, in order to guarantee the accuracy of the examination the procedure should be started from the beginning.

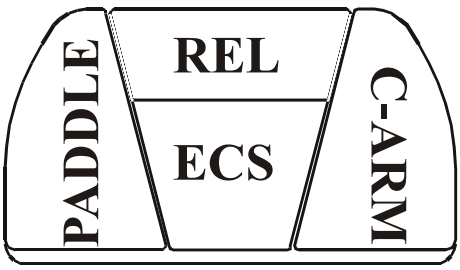
3.6.1 ECS - Easy Compression System

The **ECS - Easy Compression System** adds one more movement to the mammography system: the direction defined by the image receptor and the X-ray tube.

This movement is independent of the angle of the C-Arm, so it is different from the normal up and down movement of the carriage.

The movements are controlled with an ECS foot pedal.

After an exposure the autorelease will drive both the compression as well as the C-Arm.



The ECS uses the natural mobility of the breast to increase the clinical image quality and patient comfort.

The ECS makes it easier to elevate the breast and open the inframammary fold. Therefore it maximizes the amount of breast tissue visible in the image. In positioning the ECS will not replace the technologist but helps her to do positioning more easily.

In clinical use the amount of images that have pectoral muscle visible in cc-projections has increased from 20% (the amount prior to the use of the ECS) to 50%.

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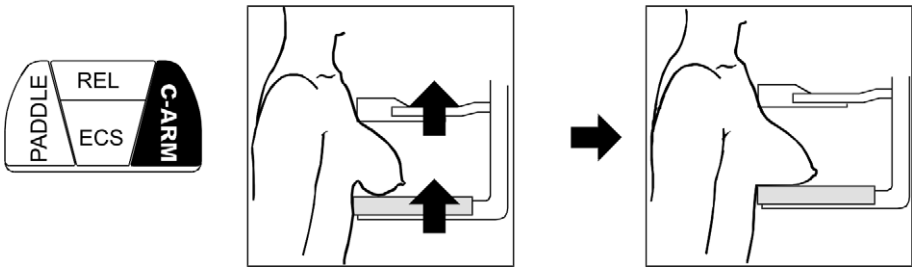
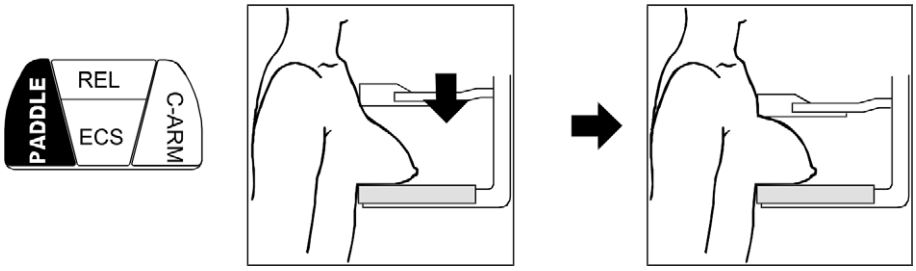
The ECS is excellent in biopsies. If the lesion is close to the chest wall, applying compression from down below ensures that the lesion stays under the compression paddle. With standard compression the lesion might may move away from underneath the paddle.

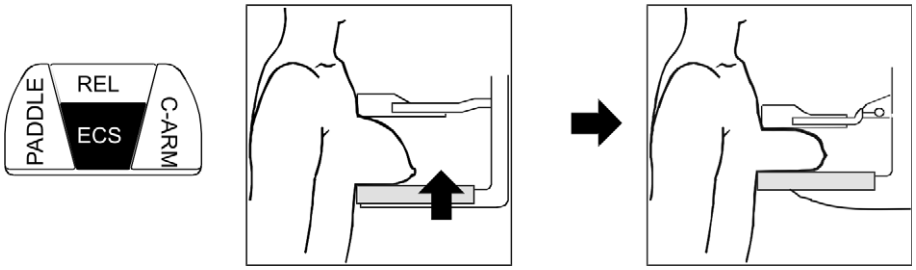
1 C-Arm is driven up without compressing to open the inframammary fold



2 The breast is compressed **slightly** with the paddle to hold it in place



3 Final compression is applied with the **ECS** from below



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3.6.2 Cranio-Caudal Projection

1 Select the desired image size.

2 Load the film into the cassette and place the cassette into the cassette holder.

3 Turn the C-Arm to the upright position by pressing the image angle release button so that the scale of image angle shows zero.

4 Adjust the cassette holder to a suitable height so that the nipple is in profile and that no skin folds are present under the breast with the vertical drive control. See figures 3.9, Correct vertical position and 3.10, Incorrect vertical position.

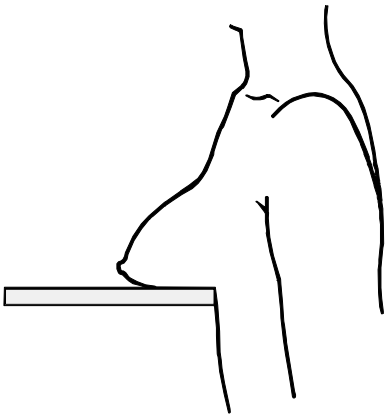

Fig 3.9. Correct vertical position

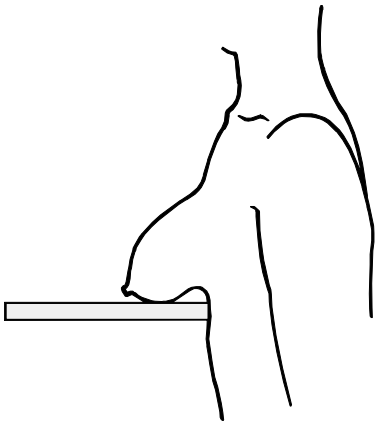

Fig 3.10. Incorrect vertical position

5 Slightly rotate the patient medially leaning towards the stand. Refer to Fig. 3.11, Patient positioning at cranio-caudal projection.

6 Allow the patient to grip with her arm under the cassette holder or the hand grips, and lean towards the stand so that the cassette holder under the breast is against the ribs.

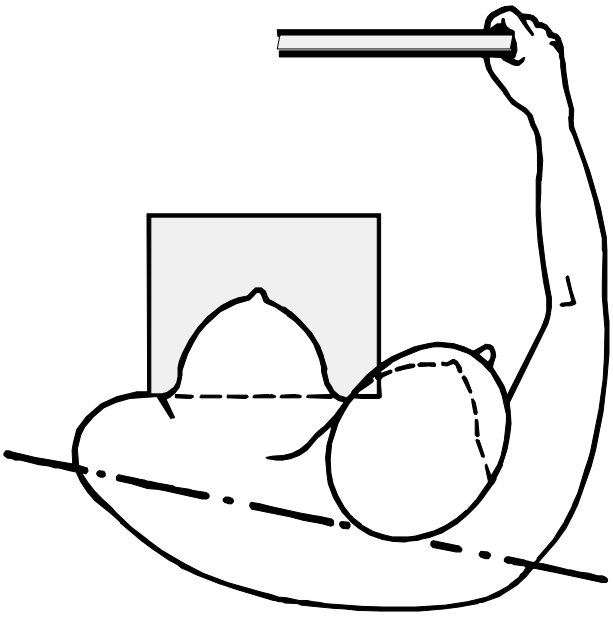

Fig 3.11. Patient positioning at cranio-caudal projection

7 Place the breast on the cassette holder so that it is symmetrical and totally covers the automatic exposure control detector, as illustrated by one of the semicircles located on the compression paddle. Ensure from the detector indicator that the breast covers the detector.

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NOTE!

If the breast does not cover the detector or the breast has an implant, manual technique must be selected.

WARNING!

Keep focal spot to skin distances as large as possible in order to keep the absorbed dose to the patient as low as reasonably achievable.

8 Set the compression with the pedal or the manual controls.

9 Take care that the nipple is not inverted. Smooth out any skin wrinkles that may have been caused during compression.

10 Place the marker on the lateral aspect of the breast. Turn the patient's head away from the radiation beam.

11 Follow the compression thickness display to achieve proper compression for both breasts. The breast should be firm when palpated. The skin may become blushed, red or pink.

12 Make sure that the **ready** light is lit. Select or de-select the **auto rel**.

Fig 3.12. Cranio-caudal projection

13 Press exposure button to initiate an exposure, and keep it pressed until the radiation indicator light is out and the audible sound is over. Then release compression.

14 Change the cassette and make an exposure of the other breast or move on to another projection.

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NOTE!

kV selected should produce an exposure time from 0.5 to 2 seconds. If exposures are longer than 2 seconds, go up in kV. If they are shorter than 0.5sec., go down in kV.

3.6.3 Latero-Medial Projection

1 Select the desired image size.

2 Load the film into the cassette and place the cassette in the cassette holder.

3 Turn the C-Arm to the lateral position by pressing the image angle release button.

4 Adjust the cassette holder to a suitable height with the vertical drive control. The woman presses her sternum against the edge of the cassette table.

5 Ask the patient to hold the hand grip and to lean against the stand.

6 Place the breast on the cassette holder so that the breast totally covers the detector of the automatic exposure control. In order to achieve this, pull the breast gently away from the chestwall.

7 Check that the breast covers the detector.

8 Set the compression with the pedal or the manual controls. Make sure that the nipple is in profile and no skin folds are present.

Fig 3.13. Latero-Medial projection

9 Check the **auto rel** and **ready** lights.

10 Press exposure button to initiate an exposure, and keep it pressed until the radiation indicator light is out and the audible sound is over. Then release compression.

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3.6.4 Oblique Projection

1 Select the desired image size.

2 Load the film into the cassette, and place the cassette in the cassette holder. Turn the C-Arm to an angle of about 45°.

3 Adjust the cassette holder to a suitable height from the vertical drive control. Place the upper edge of cassette so the axillary tail will be visualized.

4 Ask the patient to hold the arm at a 90-degree angle and turn the patient slightly to an oblique position. Rotate the patient towards the cassette.

5 Place the breast on the cassette holder so that the breast totally covers the detector of the automatic exposure control. Make sure that the lateral tissue is pulled forward.

6 Check that the breast covers the detector.

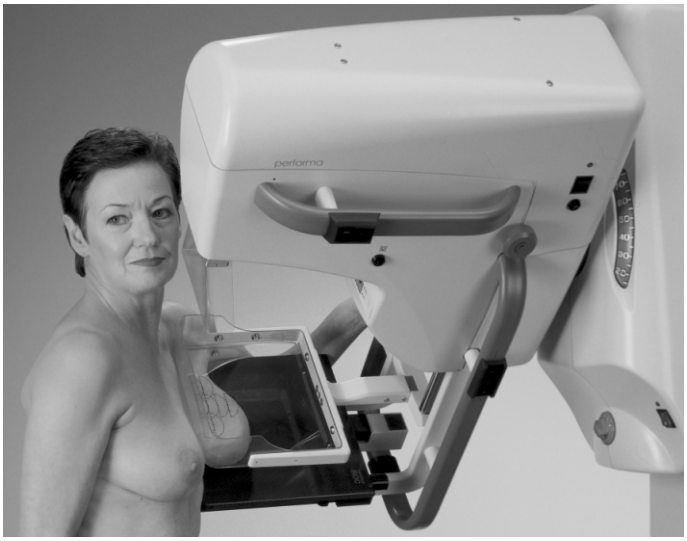

Fig 3.14. Oblique projection

7 Set the compression with the pedal or with the manual controls. Make sure that the nipple is in profile and that no skin folds are present.

8 Check the **ready** and **auto rel** lights.

9 Press exposure button to initiate an exposure, and keep it pressed until the radiation indicator light is out and the audible sound is over. Then release compression.

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3.7 EXPOSURE PROCEDURE

3.7.1 Cassette insertion

1 Load the film into the cassette.

2 Push the cassette lock backwards to insert the cassette into the cassette holder.

3 Slide the cassette in until the lock returns to the normal position.

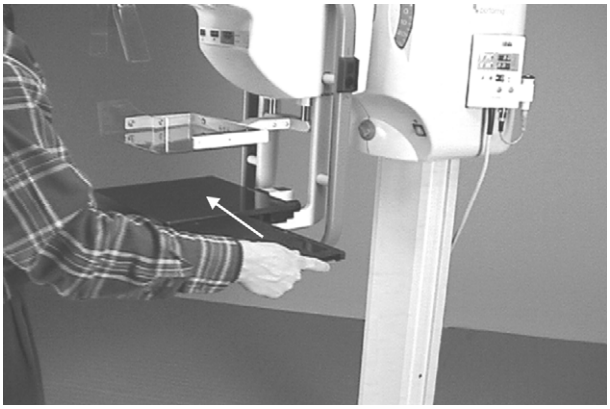

Fig 3.15. Cassette insertion

3.7.2 Making exposure

The **Ready Light** indicates that the unit is ready for exposure. The diaphragm, cassette holder and cassette must be in place.

After each exposure, there is a **cooling period** 10 - 50s depending on tube loading. During this time an exposure cannot be made. If the exposure button is pressed before this time is over, the timer display will indicate the remaining cooling time.

If the **Ready** light does not turn on 50 seconds after an exposure, read section 5.2, Ready light not lit.

NOTE!
Check that the proper filter is selected.

Press exposure button to initiate an exposure, and keep it pressed until the radiation terminates. The radiation is indicated by the radiation light, audible sound, and running exposure time on the control panel.

If the exposure button is released during the exposure, the exposure is terminated and an "**r.EL**" error message is displayed on the timer display.

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3.7.3 Cassette removal

Remove the cassette by pushing the cassette lock back from one side of the cassette holder, and pushing the cassette from the other side.

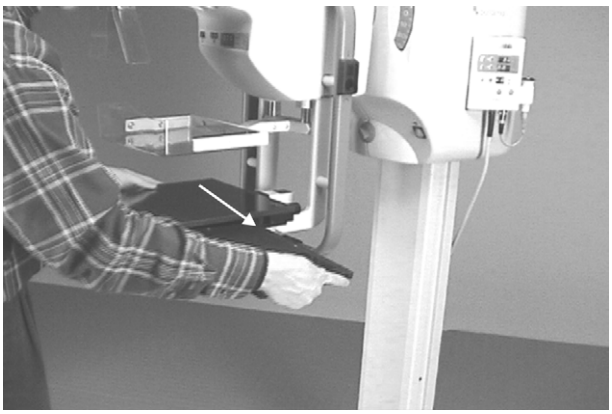

Fig 3.16. Removing the cassette

3.8 LABELING AND PRINTER CONNECTION

The Performa can output information to a printer. In this way, printed film identification labels can be produced. One of two printer label sizes can be selected by your service technician:

- 36.7 x 101 mm
- 26.0 x 101 mm

For each of the four rows printed, the last 15 characters of the 40 on each row are freely programmable. The following is an example of the text produced by Performa and printed on to a label:

```
1234567890123456789012345678901234567890
B Rh 0.02s 28kV 002mAs +0 HOSPITALxNAMEx
6.5cm 200N 180^/R 0.06mGy CODExxxxxxxxxx
15 / 08 / 00     R1 12345 RADIOLOGISTxxx
_____________________________ DEPARTMENTxxxx
```

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	Explanation
B	**B**ucky / **C**assette tunnel / **M**agnification
Rh	**Rh**odium / **Mo**lybdenum filter
+0	Density correction
28kV	kV
002mAs	mAs
0.02s	Exposure time
6.5cm	Breast thickness
200N	Compression force
180^/R	C-Arm tilt angle, ^= degrees (°), to the **/R**ight or **/L**eft
0.06mGy	Average patient dose
15 /09 /04	Date of examination (day/month/year)
R1	Site of the detector (L1, L2, C1, C2, C3, C4, R1, R2)
12345	Exposure counter, up until 99999
_____	The patient's name must be handwritten after printing the label

Printer is connected with a serial communication cable. Performa serial port is located in the back of the unit, back cover bottom left.

Use digital film flasher to print the information permanently onto film.

3.9 SPECIAL EXPOSURES

3.9.1 Magnification exposure

By having the breast at a distance from the film causes the image to be magnified. This increases the size of the smallest objects (microcalcifications) above the grain size of the film-screen combination thus improving the image quality.

Absorption in the air gap reduces scatter radiation thus further improving the contrast. Good image quality requires a small focal spot though and therefore a true 0.1mm focus is needed.

Although the object may be visualized well, this is offset by the fact that only a small area of the breast can be imaged at a time. It therefore a matter of opinion which magnification factor is used.

With the Performa system magnification factors 1.6x, 1.8x or 2.0x can be used. The magnification is determined by the magnification stand. The higher the factor is the larger the object is on the film but the area imaged from the breast is smaller.

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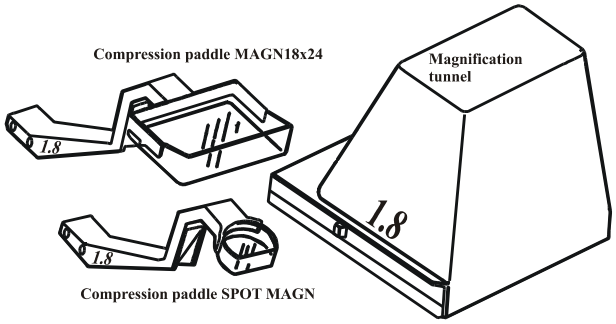
The magnification studies always use the smaller film format, 18x24. Both cassette types, normal cassette and daylight cassette can be used.

The magnification studies can be done by applying compression to whole breast which gets imaged or by applying compression only to a specific area, spot compression.

In the whole field imaging a larger area can be studied from one image, for example when it is not quite sure where the area of interest is in the breast.

Install the magnification tunnel as shown in Fig. 3.3, Replacement of cassette holder. Remove the face shield.

The "magn" indicator lights up and the default technique is selected automatically.



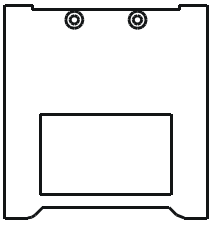
Follow the general patient positioning procedure. The size of the top of the magnification tunnel corresponds to the area which can be magnified onto the 18 x 24 film size.

If you are using magnification spot compression technique, be sure that the area of interest is in the light field and the AEC detector is closest to the patient and in the middle position.

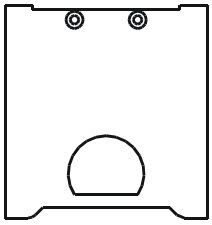
The microfocus is automatically selected in magnification exposure.

Spot compression, on the other hand, applies local compression to a particular area. This moves the different tissue structures better from hiding each other.

It also compresses the breast to thinner from this region, thereby allowing the use of lower kV-setting resulting in a better image quality. Positioning using the spot compression is more difficult though.



Magnification diaphragm, 18x24



Magnification spot diaphragm, 18x24

When using the whole film area the magnification diaphragm on the left has to be used. When using the spot compression the same diaphragm can be used or the specific spot diaphragm, on the right, can used.

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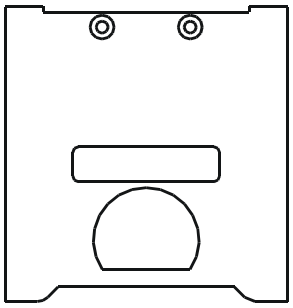
The **spot diaphragm** collimates the image area to about 12cm in diameter. This reduces scatter radiation to the image area improving contrast and also the patient dose.

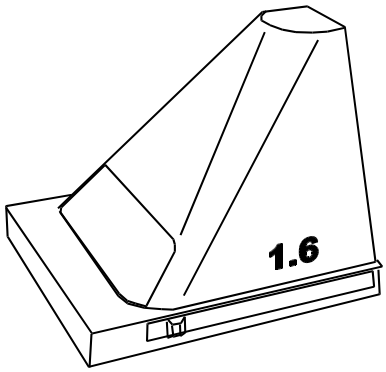


Magnification spot diaphragm for film marking

However, the final image may be harder to look at on the viewing box due to the density difference between the image and the unexposed area.

If film marking needs to be used when performing a spot compression, a special diaphragm with an opening may be used.

Spot compression can be further enhanced by using the **spot magnification tunnel**.

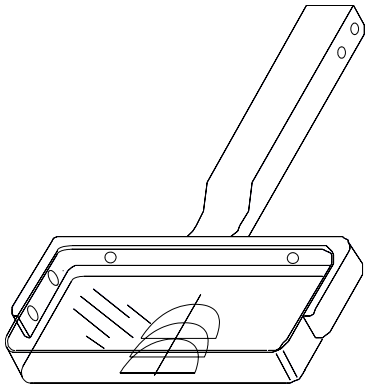


It allows the same kind of effect in compression but also from below the breast, not only from the compression paddle.

The benefits are the same, increased local compression enhancing tissue visualization and improved contrast because a lower kV setting can be used.

3.9.2 Implant exposure

The implant paddle gives a very good access to the breast during positioning.



The paddle can be best utilized with small breasts, with breasts that have a silicon implant or with male breasts.

It also allows good compression in oblique or lateral views, because it extends to the whole width of the small film format.

In regions where women usually have small breast the implant paddle may be used a standard paddle together with the 21x24 paddle.

The paddle can be used with a standard diaphragm which exposes the whole film or with the special diaphragm which exposes only the compressed part of the breast.

NOTE!

If the breast does not cover the detector or the breast has an implant, manual technique must be selected.

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3.9.3 Biopsy

1 Select the image size required and the corresponding diaphragm.

2 Attach the biopsy compression paddle.

3 Clean the compression paddle and breast area carefully. If the Laser guide is used, read the separate operation instructions.

CAUTION!

Do not use automatic release. Press AutoRel so that the indicator is “off”.

4 Turn the C-Arm to the cranio-caudal position by pressing the image angle release button. The indicator for image angle shows zero.

5 Make the patient comfortable in the sitting position. Adjust the cassette holder to a suitable height with the button for vertical drive control.

6 Place the breast on the cassette holder so that the breast totally covers the detector of the automatic exposure control. Turn the patient’s head to the side. Set the compression with the pedal or manual controls.

7 Take care that the nipple is in profile and no skin folds are present. Do not compress the breast as tightly as in a routine exam since it must remain compressed until the film is developed. Be sure to keep the patient’s head out of the light field.

8 Press exposure button to initiate an exposure and keep it pressed until the radiation indicator light turns off and the audible sound stops. Do not release the compression.

NOTE!

In case the patient moves in the middle of a procedure or compression thickness is changed, in order to guarantee the accuracy of the biopsy, new image should be taken or the procedure should be started from the beginning.

9 Develop the film. The holes in the compression paddle can be seen on the image, and localization of the biopsy target can be made. Perform the biopsy and release the compression.

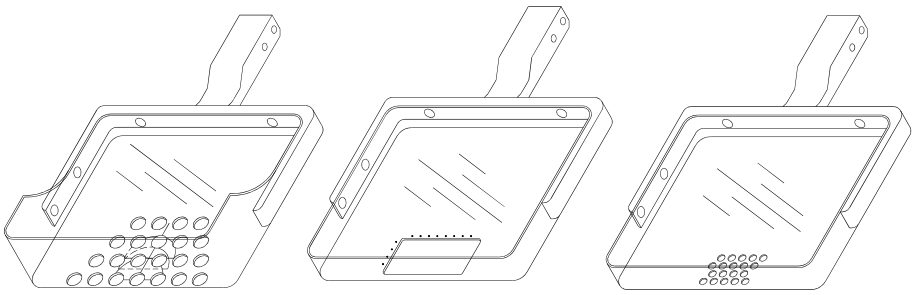

Fig 3.17. Optional biopsy / needle localization paddles

Biopsy paddles are used in manual biopsy for Fine Needle Aspiration (FNA) or lesion marking.

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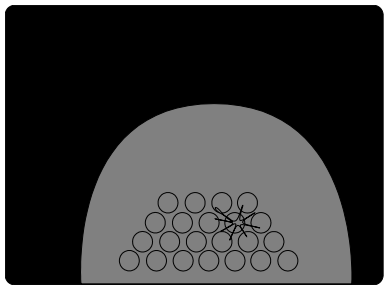


In the FNA a sample of the breast tissue is taken for cytolocigal analysis of the lesion. In lesion marking the lesion marked for surgical biopsy either with a steel wire or with carbon or a dye (color). The surgeon then follows either the wire or color trail to remove the correct lesion.

In a procedure the breast is imaged with a biopsy paddle from one projection.

The openings from the paddle can be seen in the image and with their help the location of the lesion in this plane can be estimated. How deep in the breast the lesion is can be estimated from images that have been taken using another projection. These can be taken earlier or during the same procedure.

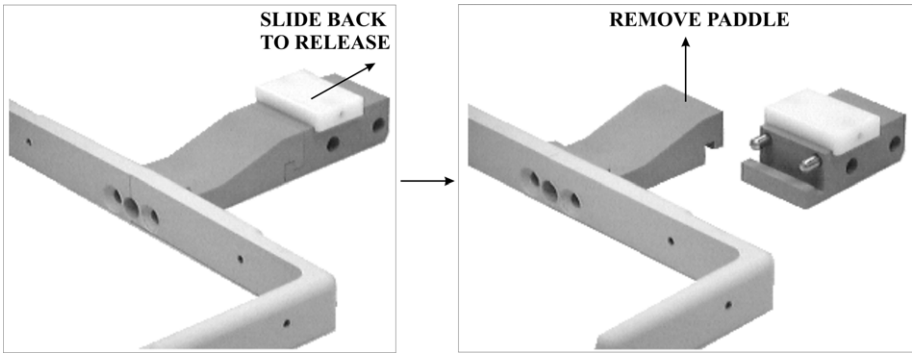
NOTE!

Continued tapping of the footswitch is improper usage of the automatic compression. Use the light switch to turn the collimator light on.

The needle is inserted into the breast after careful estimation and another image is taken to ensure proper localization.

When localizing a steel wire, it correct localizing can be imaged after insertion using another view. If this is done, the amount of compression has to be little to make sure that the wire does not move.

There are three kinds of biopsy paddles available with different openings, holes with diameter of 18mm, holes with diameter of 9mm and a square opening of size 50x90mm. Which one to use is decided by the doctor's preference.



For localization use the biopsy paddle can have a fast release arm which makes it easier to remove the paddle while the localizing wire is left in the breast.

When inserting the needle into the breast the cross hair diaphragm can be used to help the insertion.

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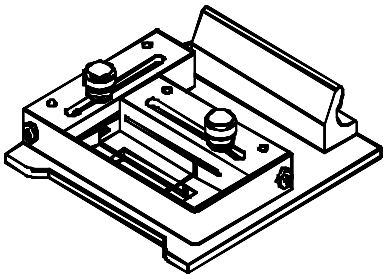
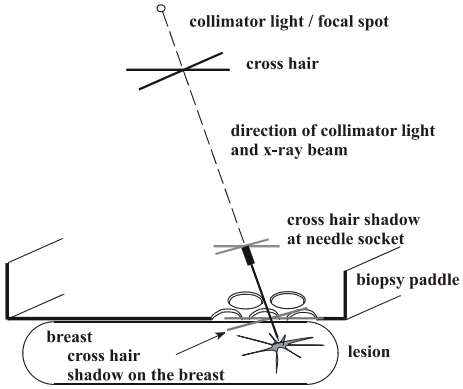
The cross hair diaphragm has two perpendicular steel wires that can be moved within the diaphragm opening to cast a cross shadow from the collimator light onto the breast.



When doing manual biopsy with a biopsy paddle the location of the lesion is observed from the film.

The location is seen with respect to the openings of the paddle.



The collimator light is turned on and the shadow from the steel wires is then moved to the corresponding location on the paddle.

The needle tip is first placed to place where the cross hair shadow is on the skin. Keeping the shadow then positioned to the other end of the needle while inserting the needle into the breast makes sure that the needle is following the same angle as the x-rays. This removes at least one uncertainty when inserting the needle manually.

Marking the lesion

NOTE!

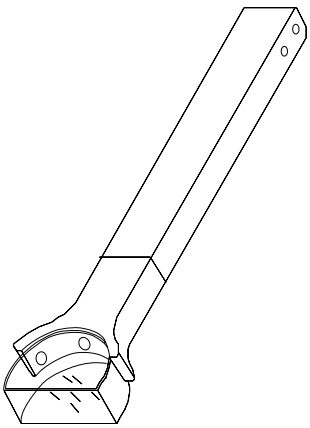
Release compression manually so that the hub of the needle does not catch on the localizer paddle.

The spot of the lesion is marked with steel wire. It is recommended to use the fast release needle localization paddles. The location of the wire end is checked with a new exposure. If needed, the location of the wire is changed and controlled with another exposure. Fix the control wire to the breast with tape.

3.9.4 Spot exposure

The spot compression paddle is used in clinical studies with bucky or cassette tunnel. It applies local compression to a specific area in the breast.

This moves the different tissue structures from hiding each other giving a better visualization. The breast tissue at the compressed area is also thinner allowing the use of a lower kV setting which gives a better contrast.



Spot compression paddle (straight arm)

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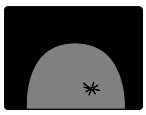
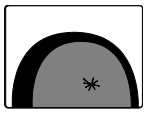
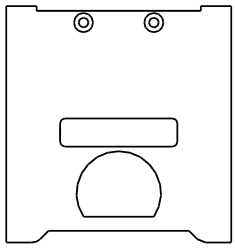




Normally the whole film is exposed to make it easier to read on the light box. However, if desired the x-ray field can be collimated to a smaller area. This reduces the patient dose because only a part of the breast gets radiation. Also, the contrast is improved because the amount of scatter radiation is reduced. However, films exposed this way are more difficult to read because of the large unexposed area.

Certain diaphragms have an additional opening for use with a film marker.



1 Select image size 18 x 24. Insert the cassette, spot diaphragm and compression paddle.

2 Turn the C-Arm to the proper angle for the projection to be performed.

3 Adjust the cassette holder to a suitable height with the button for vertical adjustment.

4 Place the detector of the automatic exposure control closest to the patient and be sure that the exposed area is under the paddle and that it covers the AEC detector.

5 Adjust the compression with the pedal or manual controls. Smooth out any skin wrinkles that may have occurred during compression. Turn the patient's head out of the light field.

6 Press exposure button to initiate an exposure, and keep it pressed until the radiation display indicator light turns off and the audible sound stops.

NOTE!

Care must be taken not to overcompress the breast and risk injury to the patient.

3.10 Transportation of Performa

If the mammography system is transported in a car or longer distances, the C-Arm has to be removed. The carriage does not tolerate the additional stress from such transportation.

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4 Integrated Quality Control test

The Performa has the Integrated Quality Control test to maintain the optical film densities the same even if the film processor conditions have changed.

Performa can correct the exposure times up to ±40%, (±25% in Germany) whereafter the unit gives the CPS error code (Check the film processing system).

The IQC can be done in two ways:

1 Reading density of the film processor sensitometry film (no exposure with Performa)

2 Taking a phantom exposure with Performa and reading the film density thereof.

Which method of IQC is used is determined in the setup of the Performa by the service technician.

NOTE!

Always use the same cassette for IQC, set the detector in the same position and read the O.D. from the same place of the exposured film.

Entering the program

The IQC-mode can be entered from the Performa by first selecting the Auto kV mode (**AA**) or Semi AEC mode (**A**) and then pressing the **+mAs**-button for **three seconds** in the Performa control panel.

NOTE!

The compression paddle drives automatically to the upper limit. This is to prevent exposures to a patient.

The timer display indicates **iqc** for one second. Then for about two seconds the correction factor from the previous IQC procedure is shown and thereafter the text **iqc** shows up again.

The mAs display shows the optical density value that is followed either the sensitometer method or the test exposure method.

NOTE!

If the compression paddle is not in the upper limit, the exposures are inhibited, the **iqc** display starts to blink and paddle drives up again.

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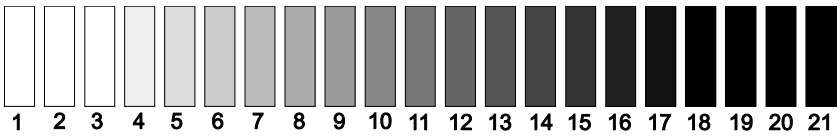
4.1 IQC WITH THE SENSITOMETRY TEST FILM

1 Expose a film with the sensitometer and process the film to get the stepwedge on the film as below:



2 Read the optical density from the step that has been selected during the installation.

3 Select Auto kV mode (**AA**) or Semi AEC mode (**A**). Press the +mAs button for three seconds. Enter the measured optical density by using the +/- density buttons. Press **Autoexp**-button to enter the value.

The time display shows the calculated correction whereafter the system returns to normal mode and is ready for use.

4.2 IQC BY USING PHANTOM EXPOSURE

1 Select Auto kV mode (**AA**) or Semi AEC mode (**A**) and press on the +mAs button for three seconds.

NOTE!

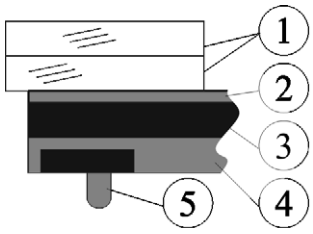
Performa selects the filter that has been programmed as default filter when switching on the unit.

The mAs display in the Performa control panel shows the text "**P.HA**" to indicate the use of a phantom.

The actual thickness of the acrylic phantom is not important as long as the same phantom is always used. If the user does not have any particular phantom to use and uses plain acrylic, thickness from 40mm to 60mm is recommended.

Placing the acrylic phantom

Place the phantom onto the cassette holder (Bucky). Having the acrylic overlapping makes sure that no stray radiation hits the detector.



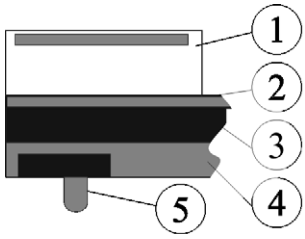
1 Acrylic/Mammographic phantom

2 Cassette holder top

3 Cassette

4 Image receptor

5 Detector



If a mammographic phantom (lower image) is used (for example RMI 156), place it flush with the cassette holder edge. This is necessary to visualize all objects in the phantom.

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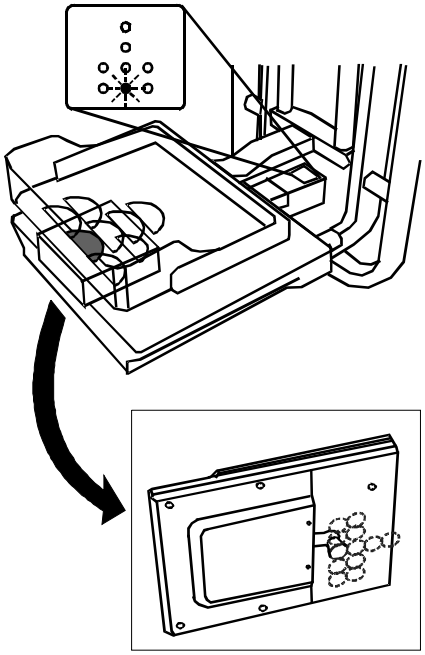
However, if the IQC results vary from procedure to procedure, check that the phantom does not let direct radiation to the detector: the phantom may have moved inwards from the cassette holder edge. Check also the placement of the detector.



Test exposure

Make an exposure, develop the film and read the optical density. Read always the optical density from the same place of the exposured film. At this stage it is possible to go out from the program by pressing the **Autoexp**-button.

Programming the measured optical density

Feed the measured optical density to the unit with the +/- **DENSITY** buttons. The Performa unit selects **1.30** as default value, but the value can be reprogrammed by the service technician.

Press **Autoexp**. The unit is now recalibrated to produce images with the wanted optical density. The new correction factor will be displayed on the timer display for 2 seconds, after that the Performa automatically returns to the mode from where the System Control mode was entered.

The optical density will be ±10% within the wanted value.

After the IQC test, verify that the phantom image O.D. lies within the country-specific limits, e.g. 1.60 ±0.15.

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5 Problem situations

5.1 No power indication

A Check that power cord and display cable are connected.

B Check that the mains switch is switched on.

C Check the fuses or the circuit breaker

D If not cleared, call service.

5.2 Ready light not lit

Depress the exposure button, and observe the text shown in the **timer** display and refer "Check code guide" on the next page.

5.3 Grid lines

If the grid light on the control panel is not lit, check that the Bucky is properly attached on the cassette holder base. Exposure time too short (shorter than 0.2 sec.). Lower the kV to extend the exposure time.

5.4 Compression paddle stuck in upper position

Compression has driven in upper position with high speed after power failure. Release compression by turning manual control handwheel clockwise hard enough.

5.5 Check and error conditions

The **Ready** light indicates that every part of the unit is ready for exposure. If the light is not on within 50 seconds after the previous exposure or the light is blinking, an error condition has been detected.

Error conditions are indicated by a code on the **timer** display.

There are two groups of codes:

Check codes indicated by **C.xx**. Check codes indicate conditions that can be handled by the operator.

Error codes indicated by **E.xx**. Most error codes require a call to the service personnel.

All possible conditions and the action required by them are listed on tables 5.1, Performa check code guide, 5.2, Performa error code guide and 5.3, Performa AEC adjustment quick fix guide.

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5.6 PERFORMA CHECK CODE GUIDE

Check code in timer display	Reason for error	Corrective action
C.CA	The film cassette is not inserted or has not been replaced since the previous exposure.	Insert or replace the film cassette.
C.CH	The cassette holder is not installed or fully engaged.	Install or re-attach the cassette holder.
C.CO	The diaphragm is not properly in place or has wrong size for the film format.	Push the diaphragm lever properly in place or re-attach the diaphragm in collimator. Use the right diaphragm.
C.dE	The technique selected resulted in too short an exposure time. The detector was not fully covered by the breast.	Press AutoExp to clear the error code. Decrease the selected kV and/or reposition the detector.
O.Fl	Back-up timer. The technique selected resulted in too long an exposure time or the detector is covered by other tissue than breast tissue.	Press AutoExp to clear the error code. Increase the kV and/or reposition the detector.
O.Fl and flashing kV-display	Exposure terminated early because calculated exposure time would have exceeded the back-up time with the selected technique.	Press AutoExp to clear the error code. Increase the kV and/or reposition the detector.
r.EL	The exposure button was released too early.	Press AutoExp to clear the error code.
r.ES	The system has reset.	Press AutoExp to re-initialize the unit.
U.FL	Direct exposure to the cassette holder or radiation is totally blocked to the detector.	Press AutoExp to clear the error code. Check the object and/or the diaphragm. Increase kV.

Table 5.1 Performa check code guide

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Check code in timer display	Reason for error	Corrective action
C.bU	The bucky grid is not in starting position.	Switch the unit off and on, re-attach the bucky. If the code re-occurs call for service.
C.Cn	The bucky grid is not moving properly.	Switch the unit off and on, re-attach the bucky. If the code re-occurs call for service.
C.ES	The exposure switch was pressed when the power was turned on.	Switch off the power. Check the exposure switch and turn on the power.
C.PS	IQC system limit reached.	Call for film processor service.
C.br	Brake released during exposure.	Check that patient has not pressed the brake release button.

Table 5.1 Performa check code guide

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5.7 PERFORMA ERROR CODE GUIDE

Error code in timer display	Reason for error	Corrective action
E.r1	Error in EPROM.	Press autoexp/call service.
E.r2	Error in EEPROM.	Turn OFF/ON, call service.
E.r3	Error in ext.RAM.	Turn OFF/ON, call service.
E.r4	Eprom error in C-Arm.	Call Service.
E.r5	EEprom error in C-Arm.	Call Service.
E.01	mA too low.	Turn OFF/ON, call service.
E.02	No kV.	Turn OFF/ON, call service.
E.03	X-ray tube too hot.	Wait 20-45 min, try making exposure. Call service.
E.04	Error in serial communication.	Turn OFF/ON, call service.
E.05	Limit counter.	Call Your distributor.
E.06	PC communication problem.	Call service.
E.07	Anode not rotating.	Turn OFF/ON, call service.
E.08	Breast thickness measuring problem.	Turn OFF/ON, call service.
E.09	Filter not in the right position.	Check filter selection mechanics.
E.10	Compression force measurement error.	Drive compression to upper limit and then drive it down. Call Service.
E.11	C-Arm angle measurement error.	Call Service.
E.12	Internal communication error.	Call Service.
S.YS	CPU error.	Turn OFF/ON, call service.
t.oF	Motor time out error.	Turn OFF/ON, call service.
E.AF	Communication error CPU - AEC.	Turn OFF/ON, call service.

Table 5.2 Performa error code guide

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5.8 AEC ADJUSTMENT QUICK FIX GUIDE

AEC adjustment quick fix guide			
Problem	**Probable reason**	**Ask service to do**	**Comments**
No contrast with large breasts	Full AEC kVs with large breasts too high.	Increase the **Target time** with large breast thickness. (Pr# 65 tAr program)	Results in lower kV with large breasts.
No contrast with small breasts.	Full AEC kVs with small breasts too high.	Increase the **Target time** with small breast thickness. (Pr# 65 tAr program).	Results in lower kV with small breasts.
mAs too high, long exposure times	Full AEC kVs low	Decrease the **Target time** values	Low kVs yield long mAs
O.fl errors or “white images”	Start kV too low and/or maximum allowable kV change too small.	Change the full AEC kV table (Pr# 64 SUP parameter E) or Increase the kV change value (Pr mode)	
EAf errors	Poor connection between CPU and AEC boards. Incorrectly adjusted AEC offset voltages.	Check the cabling. Adjust the AEC board offset voltages.	
EAf error at start up	AEC board supply voltages problems or autozeroing circuit does not work at start up.	Check the AEC board supply voltages. If you are using the 32315 AEC board with software 7.27 or later, you can remove the capacitor C35 (22µF)	
“white images”	O.fl, U.fl or C.cn error code	Check the bucky connection (apply compression)	

Table 5.3 Performa AEC adjustment quick fix guide

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5.9 PERFORMA TECHNIQUE GUIDE

SemiAEC, Mo/Mo or Mo/Rho

Film:Kodak Min R 2000, Screen: Kodak Min R 2000 and Min R 2190 Film: Fuji AD-M, Screen: Fuji AD Mammo Fine Film: Agfa HDR and HDR-C, Screen: Agfa HD and HD-S			
Compressed breast thickness	**Technique**		
	kVp	**Filter**	**Density**
< 3 cm	23	Mo	0
4 - 5 cm	24 - 26	Mo	0
6 - 7 cm	27 - 29	Mo or Rh*	0
> 8 cm	30 - 32	Mo or Rh*	0
Manual Techniques		**mAs**	**kVp**
Small breasts		16 - 40	23 - 25
Implants		80 - 175	26 - 29
Specimens (non-mag and mag)		4 - 16	20 - 23

Table 5.4 Performa technique guide

NOTE!

Implant displaced views and specimens may be phototimed if sufficient breast tissue covers the photocell closest to the chest wall.

Comments:

1 Maintain exposure times between 0.5 and 2.5 seconds. Decrease kVp if times are less than 0.5 seconds and increase if they are more than 2.5 seconds.

2 If exposure times are within indicated times, use + or - density settings to achieve optimal film density.

3 Your technique may vary from those indicated above depending on film density preferences, processor or film irregularity, or different film/screen combinations.

4 ***Rhodium** - use for very dense breasts, 6 cm or greater. No need to increase kV.

5 **Magnification views** - increase technique by 2 - 3 kVp, if exposure time exceeds 5 seconds.

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6 Specifications

6.1 System specification model MGF-110

System specifications model MGF-110	
Manufacturer	GE Healthcare Finland Oy Kuortaneenkatu 2 FIN-00510 Helsinki, Finland
Manufacturer's quality system according to	ISO9001
Manufacturer's environmental management system according to	ISO14001
General	Medical electrical equipment
Model	MGF 110
Power supply	Mains plug connection, 1-phase (line, neutral and protective ground, or L1, L2 and protective ground)
Apparent resistance of supply mains	0.75Ω
Rated voltage	230 Vac ±10%, single phase, 50/60 Hz (USA) 20 A (16 A) line

NOTE!

The Performa is a cord-connected device, delivered without a plug (in some markets). Depending upon local electrical code requirements, it may be either hard-wired or plugged into an outlet. Please consult your electrician to determine the requirements, and if necessary to provide a plug which matches your outlet.

Line Regulation:	± 2% (full load)
Branch Circuit:	dedicated run 20A, 2-pole circuit breaker L1/L2 (10 AWG) Outlet per local electrical code requirements or NEMA L6-20
Grounding:	0V potential (earth), continuous wire run (not conduit)
Rated current	20 A Momentary (during exposure) 300 mA long term (otherwise)
Rated power	3.6 kVA (2.5kW)
IEC safety class	I

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System specifications model MGF-110	
IEC applied part type	B
Enclosure	IP 20
Weight	265 kg (584 lbs.)
Height	1.9 m (6.23 ft)
Operation mode	Continuous operation with intermittent loading
Radiation intensity	Typical range 1000-1200mR/ 100mA at 28kV

Environmental specifications	
Operating conditions	+10°C...+40°C Non condensing (maximum humidity 90%)
Storage and transportation	(+0°C...+35°C)
Humidity	10%...100%
Pressure	500mbar - 1060 mbar

Generator (THF)	
Manufacturer	GE Healthcare Finland Oy
Type	MGHV-200
Frequency	40 - 100 kHz
Power	Max. 2.5 kW
kV range	20 - 35 kV, tolerance ±1.5 kV + instrument inaccuracy
mA range	Focus 0.3mm 70 - 100 mA Focus 0.1mm 20 - 30 mA
Maximum mA output	Focus 0.3mm 150mA Focus 0.1mm 45mA
mAs range	Focus 0.3mm 2 - 500 mAs (600 max in U.K.): Tolerance: mAs ≤ 40: ± 4 mAs mAs > 40: ± 10%
	Focus 0.1mm 4 - 300 mAs Tolerance: mAs ≤ 40: ± 4 mAs mAs > 40: ±10%

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Generator (THF)	
Time range	Focus 0.3mm 0.05 - 5 s (6s U.K.) Focus 0.1mm 0.05 - 10 s Tolerance: ± 0.10 + instrument inaccuracy

Automatic Exposure Control (AEC)	
Solid state 15 step density selector	
Operating range	for large focus 23 - 35 kV for small focus 25 - 35 kV
Nominal shortest irradiation time	50 msec.

Performa Filtration	
Molybdenum Rhodium	0.03 mm 0.025 mm

Positioning	
Tube lock	Electromagnetic
Movement: rotation vertical	 +135(to -180°) 1200 mm (48”)
SID	600 mm (23 5/8”)

Compression	
motorized and manual	
Foot pedal protection classification	IPX1

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Recording systems	
Contact	for 18 x 24 and 24 x 30cm film
Bucky	for 18 x 24 and 24 x 30cm film
Magnification	for 18 x 24cm film 1.6, 1.8 & 2.0 exposed size 10 x 24
Biopsy	for 18 x 24cm film

Correspondence between X-ray field and image reception area	
Chest wall	0...+3 mm
Other walls	+1...+5 mm
Correspondence between collimator light field and X-ray field	≤ 5 mm any wall

Radiation field	
Maximum radiation field	24x30cm

Attenuation equivalent	
Bucky, cassette tunnel or magnification tunnel	0.25 mm Al (Total of all layers)

Standard anti-scatter grid	
Line pairs	31 or 36 l/cm (see Bucky label)
Grid ratio	5:1
ROC Grid	
Line pairs	36 l/cm
Grid ratio	equal to 6:1

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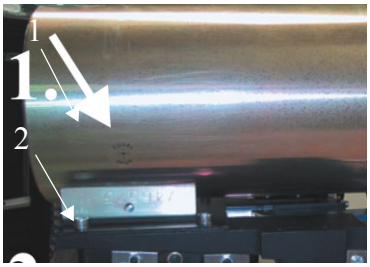
X-RAY TUBE	Varian M113SP in B112 housing
Anode type	Rotating dual-angle anode
Anode heat capacity	300,000 HU
Target material	Molybdenum alloy, niobium doped
Anode rotation speed	3000rpm(50Hz)/3600rpm(60Hz)
Focal spot sizes	M113SP 0.1, 0.3 (IEC60336)
Port material	beryllium
Reference axis	42 mm (M113SP) from chest wall edge (tube angle 4°)



1 Focal spot is marked in the front part of the tube head assembly.

2 The collimator label is at the front end of the tube head assembly.

Measurement criteria for exposure time
The **nominal x-ray voltage** 35 kV is obtained at highest tube current 70 mA.
The **nominal tube current** 70 mA is obtained at the highest tube voltage 35 kV.
The **highest tube current** 100 mA is obtained at 25 kV tube voltage.
The **highest electric power** is obtained at 32 kV tube voltage and 80 mA tube current.
The **nominal electric power** of 2.4 kW is obtained, when loading time is 0.1s, tube current at 80 mA and x-ray tube voltage at 30 kV.

Fuses		
Location	**Rating**	**Purpose**
External: Automatic fuse or F1, F2	15 A/250 V 15 ASB/ 250 V	Fuse to the 220 line Fuses to the 220 line
Supply Board		
F1	4 AT/250 V	24 VAC prior to the regulation, for AMD, C, Z and the break
F2	5 AT/250 V	18 VAC prior to regulation for the CPU and lamp

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F3	0.5 AT/250 V	15 VAC prior to regulation for the Amplifier Board
Filament Board		
F1	6 AT/250 V	24 VAC to regulators
F2	6 AT/250 V	24 VAC to regulators
Inverter Board		
F1	20AF/500V	DC-input to Inverter Board DC-input to Power Board
Anode Motor Driver		
F1	10 ASB/250 V	220 VAC to rotor

6.2 USER'S STATEMENT OF MODEL MGF 110

Radiation Leakage Technique Factors:

The maximum-rated peak tube potential is 39 kVp and the maximum rated continuous tube current is 4.0 mA (Duty cycle 1:12) for the maximum rated peak tube potential at large focal spot. The maximum-rated peak tube potential is 35 kVp and the maximum rated continuous tube current is 4.5 mA (Duty cycle 1:3) for the maximum rated peak tube potential at small focal spot.

Beam limiting device/Tube Housing assembly Compatibility:

The tube housing assembly is compatible with the interchangeable plate collimator assembly which is an integral part of the tube head and can only be used with the tube housing assembly.

Equipment Statement for Tube Housing Assembly:

Maximum operating voltage: 35 kVp effective focal spot 0.3 mm for large spot 0.1 mm for small focal spot.

X-ray tube: Varian M113SP 0.3/0.1. For additional information refer to tube specification sheets.

6.2.1 Operating Parameters

Maximum Deviation of Peak Tube Potential from Indicated Value:

±1.5 kV + instrumentation inaccuracies (1.5% of the reading + 600 V) as measured by a calibrated Dynalyzer

Maximum Deviation of Tube Current-Exposure time from Indicated Value:

±4 mAs for mAs values less than or equal to 40 mAs, ±10% for mAs values greater than 40 mAs.

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Maximum Deviation of Timer from Indicated Value:

±0.1 second + instrumentation inaccuracies (0.5% of the reading + 0.25 msec.) as measured by a calibrated Dynalyzer.

Power Supply Requirements:

Line voltage 230 VAC ±10%, 50/60 Hz, single phase. Operating Voltage Range 198-242 (±10%) Automatic regulation for all voltages within Operating Voltage Range.

Maximum Line Current:

Maximum line current during exposure is 20 A at technique factors 25 kVp and 100 mA. The system line circuit breaker is 15 A because the maximum line current of 20 A is only during short peaks during the exposure.

General Output Rating and Duty Cycle:

At 230 VAC nominal:

Large Focal Spot	100 mA at 25 kV 70 mA at 35 kV (55mA sw 7.8x)
Small Focal Spot	30 mA at 23 kV 20 mA at 35 kV

Exposures are automatically limited if the tube or housing heat capacity counter is activated.

Tube protection counter:

Anode:
Heating = kV x mAs = Joule (increased only during exposures)
Cooling = 30 Joule / sec (decreased continuously)

Housing:
Heating = kV x mAs = Joule (increased only during exposures)
Cooling = refer to diag. below (decreased continuously)

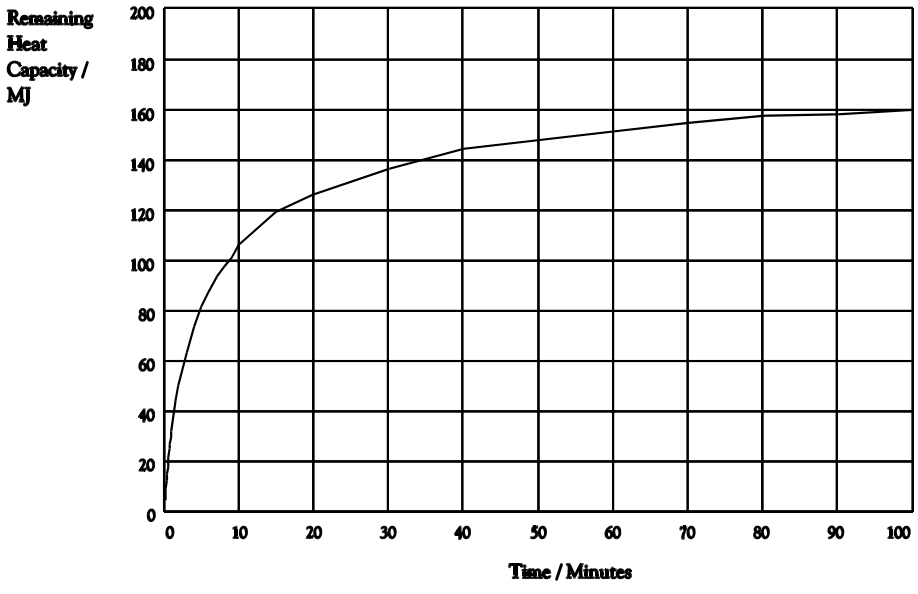

Fig 6.1. Housing cooling characteristics

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6.3 TUBE LOADING CHART FOR THE M113SP TUBE

kV	M113SP mA (SF)	M113SP (sw 7.7x) mA (LF)
20	25	75
21	26	80
22	28	85
23	30	90
24	29	95
25	28	100
26	27	95
27	26	90
28	25	85
29	24	85
30	23	80
31	22	80
32	21	80
33	21	75
34	20	75
35	20	69

Table 6.1 Maximum mAs/mA values depending on kV, focus size and country code. Software version 7.7x.

SF = Small focus, LF = large focus

Time range with loading factors shown above:

Focus 0.3	0.05 - 5.0 sec. (6.0 sec. in UK)
Focus 0.1	0.05 - 10.0 sec.

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6.4 ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

The Performa is suitable for use in the specified electromagnetic environment. The purchaser or user of the Performa should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	**Compliance**	**Electromagnetic Environment**
Radio-Frequency Emissions CISPR11	Group 1	The Performa uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
Radio-Frequency Emissions CISPR11	Class B	The Performa is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	The Performa is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	The Performa is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 6.2 Electromagnetic emissions IEC 60601-1-2

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The Performa is suitable for use in the specified electromagnetic environment. The purchaser or user of the Performa should assure that it is used in an electromagnetic environment as described below:			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment**
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	± 2, 4, 6 kV for contact discharge ± 2, 4, 8 kV for air discharge	Floors are wood, concrete, or ceramic tile, or floors are covered with synthetic material and the relative humidity is at least 30 percent.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality is that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality is that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_n for 5 sec	0 % U_n for 5 sec	Mains power quality is that of a typical commercial and/or hospital environment. If the user of the Performa requires continued operation during power mains interruptions, it is recommended that the Performa be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields are at levels characteristic of a typical location in a typical commercial and/ or hospital environment.
NOTE: U_n is the a.c. mains voltage prior to application of the test level.			

Table 6.3 Electromagnetic immunity IEC 60601-1-2

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The Performa is suitable for use in the specified electromagnetic environment. The purchaser or user of the Performa should assure that it is used in an electromagnetic environment as described below:

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment
Conducted RF IEC 61000-4-6 Radiated RFIEC 61000-4-3	3 V150 kHz to80 MHz 3 V/m80 MHz to2,5 GHz	[V_1] 3 V [E_1] 3 V/m	Portable and mobile RF communications equipment are used no closer to any part of the Performa, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended Separation Distance:** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,* are less than the compliance level in each frequency range.** Interference may occur in the vicinity of equipment marked with the following symbol:

*Field strengths from fixed transmitters, such as base stations for cellular telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be estimated accurately. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be performed. If the measured field strength exceeds the RF compliance level above, observe the Performa to verify normal operation in each use location. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Performa.

**Over the frequency range 150 kHz to 80 MHz, field strengths are less than [V_1] V/m.

The Recommended Separation Distances are listed in the next table.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6.4 RF immunity of non-life-support equipment or system IEC 60601-1-2

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Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2			
Frequency of Transmitter	**150KHz to 80 MHz**	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
Equation	$d = [\frac{3,5}{V_1}]\sqrt{P}$	$d = [\frac{3,5}{E_1}]\sqrt{P}$	$d = [\frac{7}{E_1}]\sqrt{P}$
Rated Maximum Output Power of Transmitter (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.69	3.69	7.38
100	11.67	11.67	23.34

Table 6.5 Recommended Separation Distances for Portable and Mobile RF Communications Equipment IEC 60601-1-2

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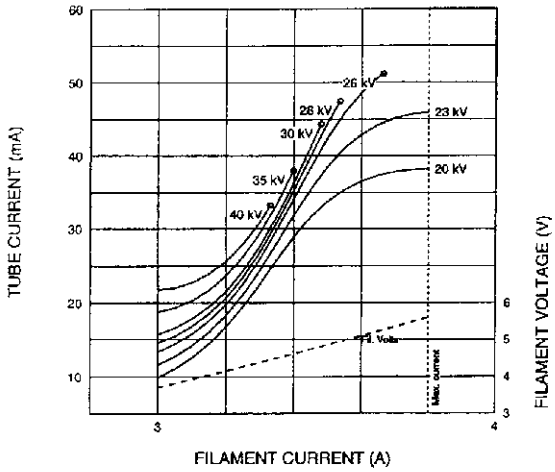
7 M113SP X-ray tube data sheets

7.1 M113SP TUBE DATA SHEET

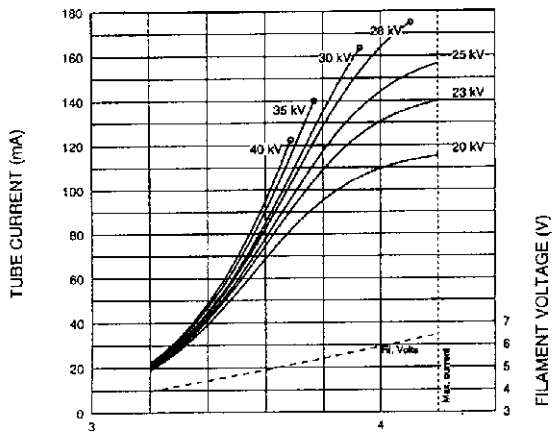
Various tube charts and markings are included in the latest revision of 5708, M113SP Rotating Anode Tube by Varian Medical Systems.

7.2 M113SP FILAMENT EMISSION CHARTS

3 Ø Full Wave



THREE PHASE EMISSION (± .15 A)
M113SP 0.1



THREE PHASE EMISSION (± .15 A)
M113SP 0.3

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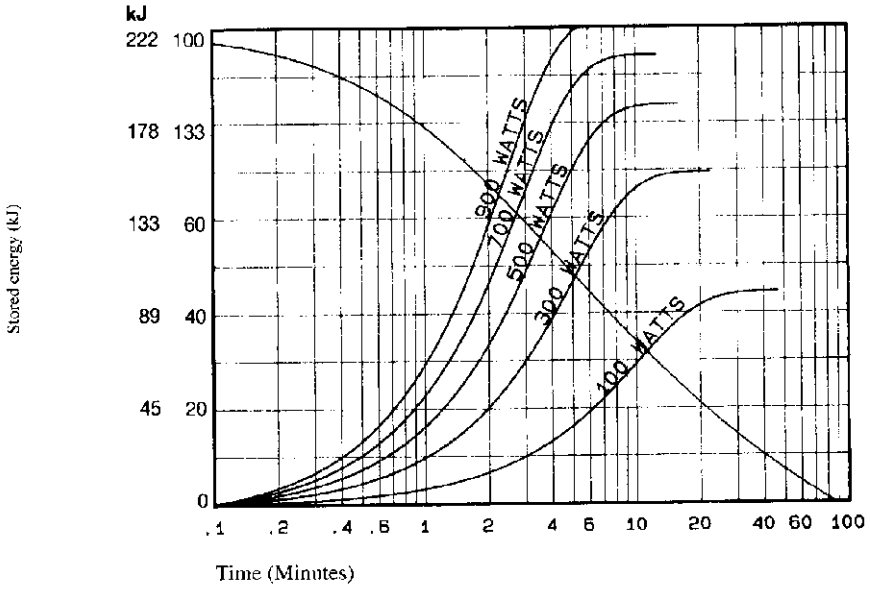
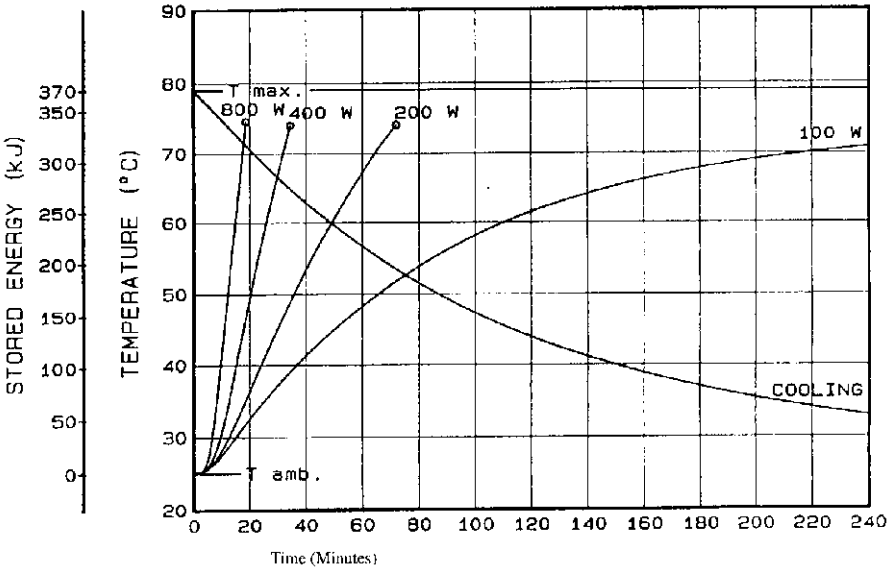
7.3 ANODE HEATING AND COOLING CURVES



7.4 HOUSING HEATING AND COOLING CURVES



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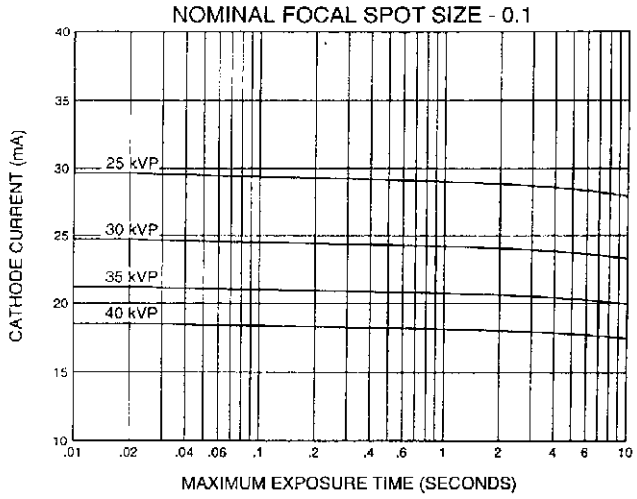
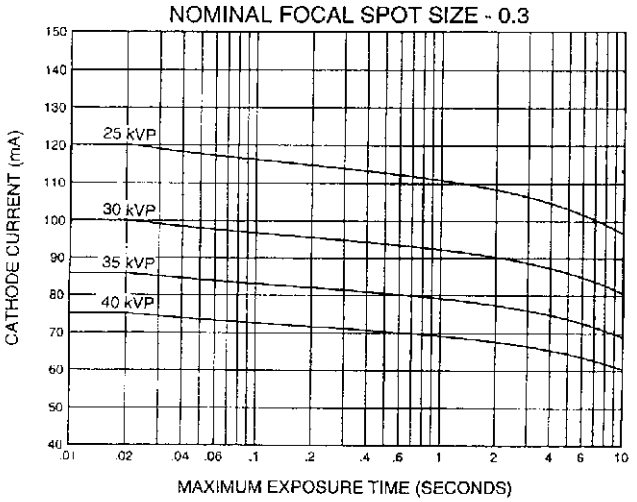
7.5 SINGLE LOAD RATINGS

7.5.1 3 Ø Constant Potential 50 Hz



0.1 ▣

M113SP RADIO 01 50 HZ



0.3 ■

M113SP RADIO 03 50 HZ

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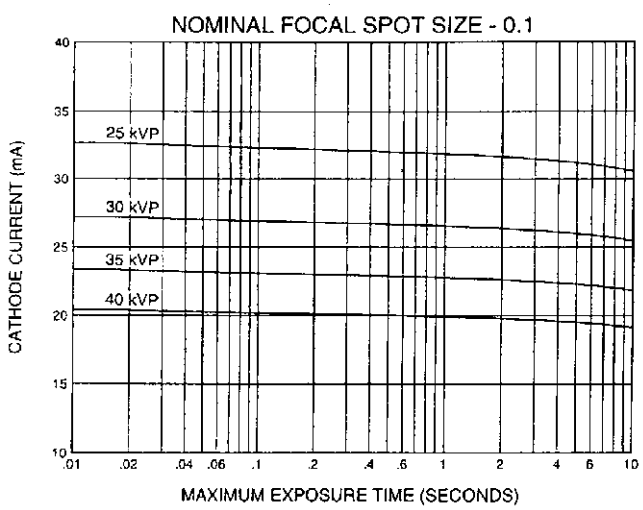
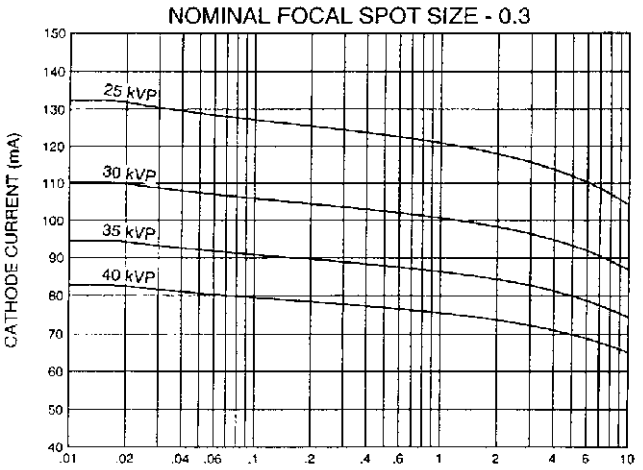
7.5.2 3 Ø Constant Potential 60 Hz



0.1 ▣

M113SP RADIO 01 60 HZ



0.3 ■

M113SP RADIO 03 60 HZ

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7.6 DESCRIPTION

The M113SP rotating anode X-ray tube is a 39 kVp VARIAN insert tube with 0.1 mm and 0.3 mm focal spot combination and 77 mm diameter bi-angular (10°/16°) Molybdenum anode disc, cathode grounded.

The M113SP metal center section X-ray tube is for use in Mammography systems. The use of a metal center section tube eliminates arcing due to metal deposition on glass and allows use of a Beryllium window in the insert for minimum inherent filtration.

7.7 GENERAL DATA

Maximum Peak Voltage:	39 kV (Anode to Ground)
Nominal Focal Spot Size:	Small: 0.1 mm (Refer to General Information Section for Focal Spot Measurement Method) Large: 0.3 mm
Maximum Anode Load:	3-phase, 180Hz, 0.1 second
Small Focal Spot:	1320 W
Large Focal Spot:	4.9 kW
Anode Disc Construction:	Molybdenum Alloy
Anode Disc Diameter:	77 mm
Anode Disc Target Angle:	M113SP (LF/SF) 16/10
Anode Heat Storage:	300 kHU
Maximum Anode Cooling Rate:	60,000 HU/minute
Inherent Filtration:	0.0 mm Alum. Equiv. 0.76 mm Beryllium
U/L Approved:	Yes

7.8 B-112 HOUSING

Class:	I
Type:	B
Maximum Peak Voltage:	52 kV
Anode to Ground:	52 kV
Cathode to Ground:	0 kV
Housing Heat Storage Capacity:	370 KJ (500 kHU)
Housing Cooling Rate:	100 Watts (135HU/sec)
Weight:	10.2 kg (22.5 lbs)
Length:	33 cm (13”)
Diameter:	13.8 cm (5.44”)
Focal Spot - Port Spacing:	Small 47.0mm +/- 1mm Large 41.4 +/- 1mm
High Voltage Cable, Special Design (Non-Federal Standard):	55 kV Rating
Acoustic noise:	50dB Max. (A-weighted) at 30 cm
Leakage Technique Factor M113SP:	52 kV, 2mA

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Leakage Technique Factor B112:	55 kV, 4mA
Minimum Ambient temperature for storage & transportation:	-9°C (16°F)
Maximum Operation Temperature:	+40°C (+104°F)
Low Voltage Cable:	
Pin Position	Function
1	Phase Shift
2	Phase
3	Common
4	Housing Ground
5	Grid
6	Not used
7	Small Filament
8	Filament Common
9	Large Filament

7.9 FILAMENTS

Focal spot	Volts	Amperes
0.1	3.8 - 7.3	3.0 - 4.8
0.3	6.0 - 10.5	3.6 - 5.2

7.10 STATOR 50/60 HZ

Starting	115 V	230 V
Amperes	4	8
Seconds to start	1	0.5
Duty	Intermittent	Intermittent

Running	45 V	90 V
Amperes	1.4 - 2.0	1.4 - 2.0
Duty	Continuous	Continuous

PHASE SHIFT CAPACITOR: 30 Microfarad

Safety: Thermal Switch

- Connected in series with stator common wire
- Opens at 79.4°C ± 3.9°C (175°F ± 7°F)
- Closes at 68.3°C ± 3.9°C (155°F ± 7°F)

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7.11 INHERENT FILTRATION

Inherent filtration of the insert is 0 mm Aluminum equivalent. For operation of the X-ray tube to 39 kV, a minimum of 0.5mm Aluminum equivalent must be added to the X-ray beam.

Leakage Technique Factor M113SP:	40 pkV, 7mA
Minimum Ambient temperature for storage & transportation:	-10°C (15°F) to +75°C (+167°F)
Operation Temperature:	+5°C (+41°F) to +40°C (+104°F)

7.12 RAYPROOFING

Stray radiation complies with the requirements of FDA 21 CFR, Subchapter J for medical diagnostic-type protective X-ray tube housings.

7.13 FOCAL SPOT MEASUREMENT METHOD

M113SP small focus:

Measured at 25kV, 20mA with one degree star pattern or a slit focal. Maximum focal spot size = 0.15W x 0.15L (mm).

M113SP large focus:

Measured at 25kV, 80mA with one degree star pattern or a slit focal. Maximum focal spot size = 0.45W x 0.58L (mm).

Specification of the maximum focal spot size limits must be performed at the techniques listed above.

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8 System maintenance

8.1 CLEANING

WARNING!

Before cleaning and disinfecting, remove power from the equipment.

ALL parts of the unit which come in contact with the patient must be cleaned and disinfected prior to each examination.

The standard hospital regimen for disinfection should be followed, with the following qualifications:

DO NOT clean surfaces on parts which contact the patient (i.e., face shield, cassette holders, Bucky devices, compression paddles) with solvent-based cleaners (containing benzene, alcohol, or stain removers).

DO NOT use extra-strength or abrasive cleaners, polishes, or waxes on parts which contact the patient.

Proprietary disinfectant solutions meeting the above limitations are suitable, provided that the manufacturer's instructions are stringently followed. DO NOT immerse the Bucky in disinfectant solution.

As a general rule, disinfectant sprays may not be used directly. The mist generated by spraying may penetrate into the unit, and this may damage electronic components. To use a disinfectant agent in spray form, first apply the agent to a clean cloth or pad, and then use the pad to apply the agent to the surface requiring disinfectant.

For general cleaning, use a non-lint cloth dampened with water, or a lukewarm, diluted aqueous solution of household dishwashing liquid.

8.2 CARE

Handle the plastic accessories carefully, and inspect them frequently. If they begin to crack, discontinue their use and replace them.

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8.3 OPERATORS MAINTENANCE SCHEDULE

The following inspections must be performed monthly by the operator of the equipment.

1 **Visual Exposure Indicator**
Confirm that the exposure indicator light stays on for the length of the exposure.

2 **Audible Exposure Indicator**
Confirm that the buzzer stays on for the length of the exposure.

3 **Exposure Switch**
Confirm that the exposure switch requires continuous pressing to maintain the exposure and that releasing of the switch terminates the exposure and that the timer display indicates “Rel”.

4 **Warning and Indicator Labels**
Inspect and confirm that all warning labels and embossed, painted or other wearable labels have not been defaced or worn and that they are legible.

5 **Automatic Exposure Control (AEC)**
Confirm that the autoexp light illuminates when AEC is selected.

6 **Vertical Movement**
Check that the carriage moves smoothly and in both directions.

7 **Compression force**
Check that the compression force has not changed.

8 **Compression release when power failure**
Check that the compression paddle drives up about 5 seconds when the mains voltage is disconnected

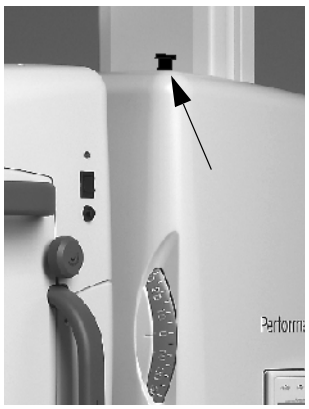
9 **Rotation Movement and angle display**
Check that the C-Arm moves smoothly in all positions. Check that the displayed angle corresponds to the selected angle.

10 **Control Panel**
Check that all buttons in the control panel are intact by noticing that all lights and display segments are lit up after connecting the main power on and pressing the reset (AUTOEXP) button.

11 **Compression thickness display check**
Place 60 mm acrylic on the cassette holder. Drive down the compression paddle against the acrylics. Check that thickness display indicates 6.0 cm. If not, call for service.

12 **Manual decompression**
Compress against an object at 200N and verify that you can decompress manually with hand wheels.

13 **Emergency buttons**
Verify that all electronically controled movements (vertical, c-arm rotation, compression) are disabled when emergency button is pressed down. All motorized movements should stop. Release the emergency stop button, switch on the unit once again and then repeat the test using the emergency stop button on the opposite side of the unit. Finally, verify that normal operation of the unit is restored once the button is back in normal position.



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8.4 PREVENTIVE MAINTENANCE SCHEDULE

The following inspections must be scheduled by the user. Only authorized and trained service technicians are allowed to carry out the maintenance on this equipment. Manufacturer can supply at request necessary documents to Instrumentarium Imaging approved service technician for repair of such parts that the manufacturer has indicated to be repairable.

Once a year	Section in installation instructions
1 kV/mAs/preheat tests.	Perform tests 4.10, 4.11 and 5.2.9.
2 X-ray and light fields.	Perform tests 5.2.11 and 5.2.12.
3 AEC adjustment.	AEC adjustment. Perform test 5.2.14.
4 Safety ground.	Verify that the metal parts of the unit are connected to protective ground.
5 Oil leaks.	Check that the high voltage unit and the tube housing do not leak oil.
6 Anode run voltage.	Perform test 4.9.
7 Compression force.	Perform test 5.2.5 and 5.2.7.
8 C-Arm rotate brake.	Perform test 5.2.3.
9 Interlock system.	Check that exposures are not allowed if the diaphragm, cassette holder or the cassette is missing. Check the error codes.
10 Clean High Voltage Connections and grease with clean grease for example DowCorning #4.	
11 Lubricate the counterweight wires with a light coat of “STP” or “CRC”. Do not apply degreasers or cleaners. Replace if broken strands are found.	
12 Tighten ground connections. Inspect crimps, connections and cables for wear or breakage.	

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8.5 QUALITY ASSURANCE

If the performance of the unit has changed, please contact your local distributor.

Distributor:				
Contact person:			Tel:	
PERFORMA serial number *):		Installation date:		
Last maintenance performed:				
Exposure counter number:				
Last maintenance performed:				
Exposure counter number:				

*) The serial number is printed on a label attached to the rear cover of the unit.

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TEST	FREQUENCY	TOOL(S)	PERFORMED BY
Film Processor	Daily	Thermometer Densitometer Sensitometer	Radiographer/ Technologist
Image Quality	Weekly	RMI 156D Phantom	Radiographer/ Technologist Physician
Phototimer Reproducibility	Monthly	Acrylic phantom	Radiographer/ Technologist Physician
Film/Screen Contact	Semi-annually	Contact test tool	Physicist or Service Technician
kVp	Semi-annually	Dynalyzer	Physicist
Dose/Patient Exposure	Semi-annually	Ion Chamber	Physicist
Half-Value Layer (HVL)	Semi-annually	Aluminum HVL set with Ion Chamber	Physicist
mAs (mA)	Semi-annually	Dynalyzer (mAs meter)	Physicist or Service Technician
mAs Linearity	Semi-annually	Ion Chamber (Digital)	Physicist or Service Technician
Compression	Semi-annually	Scale	Radiographer/ Technologist
Exposure Reproducibility (mR/mAs)	Annually	Ion Chamber	Physicist or Service Technician
Line pair resolution	Annually	Bar Pattern	Physicist

NOTE!

Refer to local regulations and instructions concerning the testing of the unit.

If the unit does not meet the manufacturer´s specifications, despite of proper maintenance and repair, the operating life of the unit has come to an end. As the used X-ray tube and oil, high voltage unit, all electronic boards and parts of lead in collimator and under the AEC detectors are toxic waste, refer to country-specific disposal instructions.

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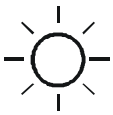
9 Graphical symbols used

	Radiographic control
	Earth (ground)
	Protective earth (ground)
	Type B equipment
	Dangerous voltage
	ON (Power)
	OFF (Power)
	Attention, consult accompanying documents
	Vertical movement up and down (Movement in both directions)
	Brake release (Rotation in two directions)
	Compression paddle up/down (Movement in one direction)
	Beam field illumination
	Compression force (Variability)
CE 0537	The unit is CE-marked according to the Medical Device Directive 93/42/EEC (if the unit contains CE mark).
CLASSIFIED C UL US	Unit (if the unit contains UL/CSA mark) is tested and certified according to UL/CSA (file E218408).
	This symbol (if marked) indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment

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